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IN THE

Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE AND GLAXOSMITHKLINE BIOLOGICALS, S.A.,

Petitioners,

v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI, Individually and as Parents and Next Friend of STEFAN R. FERRARI,

Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of Georgia

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In the 1980s, the costs and risks of product liability litigation drove several vaccine manufacturers out of the market, causing shortages of vaccines essential to public health programs. Congress averted a public health crisis by enacting the National Childhood Vaccine Injury Act of 1986. The Act shielded vaccine manufacturers from categories of tort litigation, directed federal agencies to develop safer childhood vaccines, and established a Vaccine Court to administer a no-fault remedy for vaccine-related injuries. The Act's express preemption provision states that "[n]o vaccine manufacturer shall be liable in a civil action" if the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

Does the Vaccine Act expressly preempt a state-law claim against a vaccine manufacturer based on an allegation that the vaccine-related injury could have been avoided by a vaccine design allegedly safer than the one approved by the U.S. Food and Drug Administration for use nationwide?

LIST OF PARTIES AND RULE 29.6 STATEMENT

All parties to the proceedings in the Supreme Court of Georgia are listed in the caption.

Wyeth is a publicly traded corporation. No publicly held corporation owns 10% or more of its outstanding shares.

Through its wholly owned subsidiaries, GlaxoSmithKline plc owns 100% of both SmithKline Beecham Corporation and GlaxoSmithKline Biologicals, S.A. No publicly held corporations own 10% or more outstanding shares.

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Blackmon v. Am. Home Prods. Corp.,
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Bruesewitz v. Wyeth, Inc.,
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Cox Broad. Corp. v. Cohn,
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Hazlehurst v. Sec'y of HHS,
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Militrano v. Lederle Labs.,
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United States v. Price,
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Wright v. Aventis Pasteur, Inc.,
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336 EDA 2008 (Pa. Super. Ct.) 27

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H.R. Rep. No. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344 ..... *passim*

National Childhood Vaccine Injury Compensation Act of 1985: Hearing on S. 827 Before the S. Comm. on Labor and Human Resources, 99th Cong. 145 (July 18, 1985) 8

Staff of Subcomm. on Health and the Environment, 99th Cong., Childhood Immunizations (Sept. 1986) 9, 10, 20, 24

Miscellaneous

Laura Beil, *Worrisome Infection Eludes a Leading Children's Vaccine*, N.Y. Times, Oct. 14, 2008 25

CDC, *Mercury and Vaccines (Thimerosal)*, http://www.cdc.gov/vaccinesafety/concerns/thimerosal.htm (last modified Feb. 8, 2008) 14

CDC, *Recommendation of the Immunization Practices Advisory Committee New Recommended Schedule for Active Immunization of Normal Infants and Children*, 35 MMWR 577 (Sep. 19, 1986) 24

CDC, *Recommended Immunization Schedules for Persons Aged 0-18 Years—United States, 2008*, 57 MMWR Q1 (Jan. 11, 2008) 25

CDC, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MMWR 241 (Apr. 2, 1999) 7, 8, 25

Geoffrey Evans, *Update on Vaccine Liability in the United States*, 42 Clinical Infectious Diseases S130 (2006) 19, 22

FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/cber/ vaccine/thimerosal.htm(last modified Jan. 14, 2009) 14, 23

HHS, *HRSA Awards Contract to Study Adverse Events in Childhood Vaccines* (Oct. 23, 2008), http://newsroom.hrsa.gov/releases/2008/vaccinestudy.htm 20

HHS/Public Health Service/National Vaccine Program Office, *The U.S. National Vaccine Plan – 1994* (1994) 13

Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* (2004) 15

Kashif Iqbal et al., *Haemophilus influenzae Type b Invasive Disease*, 2-1 (2008), http://www.cdc.gov/vaccines/pubs/surv-manual/chpt02-hib.pdf. 25

Walter A. Orenstein et al., *Immunizations in the United States: Success, Structure, and Stress*, 24 Health Aff. 601 (2005) 8

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) 13

Richard D. Smith, *Responding to Global Infectious Disease Outbreaks: Lessons from SARS on the Role of Risk Perception, Communication and Management*, 63 Soc. Sci. & Med. 3113 (2006) 25

PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The decision of the Supreme Court of Georgia is published at 668 S.E.2d 236, and is reproduced in the Appendix ("App.") at 1. The decision of the Georgia Court of Appeals, dated July 5, 2007, is published at 650 S.E.2d 585, and is reproduced at App. 19. The unpublished decision of the State Court of Fulton County, dated November 30, 2005, is reproduced at App. 33.

JURISDICTION

The Georgia trial court ruled that Section 22 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22, expressly preempted Respondents' design defect claims, and the court entered a partial summary judgment finally disposing of those claims. App. 42-49. The Georgia Court of Appeals reversed the trial court's order. App. 19. On October 6, 2008, the Georgia Supreme Court affirmed the Court of Appeals' order. App. 3-4. Upon Petitioners' application, on December 22, 2008, Justice Thomas extended the time to file a petition for a writ of certiorari in this case to and including March 5, 2009. This Court has jurisdiction under 28 U.S.C. § 1257(a).

The Georgia Supreme Court's decision is a final judgment for the purposes of 28 U.S.C. § 1257(a). *See Cox Broad. Corp. v. Cohn*, 420 U.S. 469, 482-83 (1975); *see also Belknap, Inc. v. Hale*, 463 U.S. 491,

497 n.5 (1983) (allowing review of a state court determination that state causes of action were not preempted by federal law). A decision not to review the Georgia Supreme Court's decision now will "seriously erode" the federal public health policies of the Vaccine Act. *Cox Broad. Corp.*, 420 U.S. at 483. The Vaccine Act's preemption of civil liability is integral to ensuring adequate supplies of vaccines necessary to protect the public from infectious disease. *See* H.R. Rep. No. 99-908, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348 [hereinafter "H.R. Rep. at __, 1986 U.S.C.C.A.N. at __"].

This case satisfies all three criteria necessary to justify immediate review of a state supreme court decision that threatens federal policy. *See Cox Broad. Corp.*, 420 U.S. at 482-83. First, the Georgia Supreme Court has finally determined that the Vaccine Act does not categorically preempt design defect claims. Second, the design defect claims could be resolved on other grounds on remand—such as the failure to prove, after trial, that the alleged injury was caused by the vaccines—depriving Petitioners of any opportunity to seek review of the preemption ruling. Third, if this Court reverses the Georgia Supreme Court's decision, the design defect claims will be conclusively resolved as preempted and will not be further litigated. The Court should not delay addressing this pressing preemption question, because the Georgia Supreme Court's decision invites litigation larger in scope than the onslaught two decades ago that impelled Congress to adopt the Vaccine Act.

CONSTITUTIONAL AND STATUTORY PROVISIONS

This case involves application of the Supremacy Clause of the United States Constitution, art. VI, § 1, cl. 2, which provides as follows:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The case revolves around the interpretation of 42 U.S.C. § 300aa-22, which provides, in relevant part, as follows:

> **§ 300aa-22. Standards of responsibility**
>
> (a) General Rule
>
> Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> (b) Unavoidable adverse side effects; warnings
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was

accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

INTRODUCTION

Congress narrowly averted a public health crisis by enacting the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.* (the "Vaccine Act" or "Act"). In a decision that avowedly rejects the position of every other jurisdiction to rule on the issue, the Georgia Supreme Court has invited that crisis back.

The crisis was an alarmingly unstable vaccine supply. As Congress declared, "[t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities." H.R. Rep. at 5, 1986 U.S.C.C.A.N. at 6346. But vaccine manufacturers labored under the strain of crushing defense costs and potential liability from several hundred product liability cases pressing "design defect" claims—i.e., claims that the manufacturer should have adopted a vaccine design different from, and allegedly safer than, the Food and Drug Administration ("FDA") approved design. The litigation strain was driving vaccine manufacturers out of the market, causing vaccine shortages, and threatening a resurgence of infectious disease. Congress stabilized the vaccine market—and averted the public health crisis—by shielding vaccine manufacturers from tort liabilities (with specified exceptions), and creating a reliable and speedy no-fault remedy administered by a special federal court (colloquially known as "Vaccine Court").

The liability shield, which is at issue in this case, is in Section 22(b)(1) of the Vaccine Act. That

provision expressly preempts *all* civil liability "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

Outside of Georgia, every court to rule on the Vaccine Act's preemption provision has correctly interpreted it to categorically preempt all claims for vaccine-related injuries unless the vaccine at issue contained a manufacturing defect (i.e., was not "properly prepared") or was inadequately labeled (i.e., was not accompanied by "proper directions and warnings"). Thus, each one of these courts rejected attempts by plaintiffs to circumvent the Act through state law "design defect" claims.

In this case, however, the Georgia Supreme Court rejected the prevailing categorical rule. It held that Section 22(b)(1) does not preclude design defect claims unless the manufacturer demonstrates, case by case, that there *was no safer design* that could have avoided the injury. Under this rule, judges and juries in every case, in every state, would second-guess the balance that the FDA and several other federal agencies strike between vaccine safety and efficacy. To reach this conclusion, the Georgia Supreme Court improperly isolated Section 22(b)(1)'s language about "side effects that were unavoidable" from the rest of the sentence, disregarding Congress's intent to characterize a side effect from an FDA-approved vaccine as "unavoidable" and therefore not subject to lawsuits *as long as* "the vaccine was properly prepared and was accompanied by proper directions and warnings." The court also disregarded the legislative history confirming that

Section 22(b)(1) was intended to provide complete immunity from suit for claims based on design.

If the Georgia Supreme Court's interpretation of the preemption provision stands, tort litigation will once again swamp vaccine manufacturers in a way that could make the deluge of 1986 seem like a trickle. There are currently more than 4,900 claims pending in an "Omnibus Autism Proceeding" in Vaccine Court. Like the claim in this case, many of these thousands of claims are premised on the notion that a child's autism was caused by FDA-approved vaccines and could have been avoided by using a different, purportedly safer design.

Under the Georgia rule, every one of these claimants would have the option to reject the Vaccine Court's judgment and collaterally challenge the FDA's approval of a vaccine's design before a jury. The few remaining vaccine manufacturers will face the expense and uncertainty Congress averted 20 years ago—but this time, dialed up by an order of magnitude. The threat to the nation's vaccine supply and to the development of new vaccines is too grave to leave for another day. This Court should review the Georgia Supreme Court's decision now.

STATEMENT OF THE CASE

A Stable Vaccine Supply Is Critical To Public Health

As recently as the middle of the 20th century, infectious diseases crippled, or even killed, tens of thousands of children a year. Into the 1950s, polio killed nearly 1,900 Americans annually, and paralyzed over 16,000. CDC, *Ten Great Public*

Health Achievements—United States, 1900-1999, 48 *MMWR* 241, 246 (Apr. 2, 1999). Measles afflicted over half a million victims a year, killing more than 400. *Id.* The highly contagious pertussis disease (commonly known as whooping cough) infected over 140,000 victims. *See* Walter A. Orenstein et al., *Immunizations in the United States: Success, Structure, and Stress*, 24 Health Aff. 601, 602 (2005).

Over the decades, public health programs to vaccinate and immunize whole populations have virtually vanquished all these infectious diseases. Smallpox was literally eradicated worldwide by 1977. CDC, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 *MMWR* 241, 246 (Apr. 2, 1999). Polio, diphtheria, and tetanus were effectively eliminated in the United States. H.R. Rep. at 5, 1986 U.S.C.C.A.N. at 6346. By the 1980s, whooping cough, measles, mumps, and rubella had been subdued by more than 98% of their peak levels. *National Childhood Vaccine Injury Compensation Act of 1985: Hearing on S. 827 Before the S. Comm. on Labor and Human Resources*, 99th Cong. 145 (July 18, 1985). Vaccines made these public health triumphs happen. It was no exaggeration when the congressional committee that reported on the Vaccine Act observed: "Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. Rep. at 4, 1986 U.S.C.C.A.N. at 6345. But, as Congress also recognized, the program requires constant attention: the continued suppression of infectious disease depends upon ongoing universal vaccination, which

depends, in turn, on a stable supply of vaccines. *Id.* at 7, 1986 U.S.C.C.A.N. at 6348.

Vaccine Litigation Causes a Public Health Crisis

In the mid-1980s the requisite vaccine supply was teetering on the brink of disaster. The root cause was a proliferation of tort cases against vaccine manufacturers. The vast majority of the cases targeted the combined pediatric vaccine for diphtheria, tetanus, and pertussis ("DTP"). Plaintiffs brought design defect claims alleging that the only FDA-approved DTP vaccine design was unreasonably dangerous, and thus defective.

The litigation threat precipitated an exodus from the vaccine market. "The number of childhood vaccine manufacturers . . . declined significantly," *id.* at 4, 1986 U.S.C.C.A.N. at 6345, while the few that remained began "to question their continued participation in the vaccine market," *id.* at 7, 1986 U.S.C.C.A.N. at 6348. As of the end of 1984, two of the three domestic commercial manufacturers of the DTP vaccine had withdrawn from the market. *See Staff of Subcomm. on Health and the Environment, 99th Cong., Childhood Immunizations* 68 (Sept. 1986) [hereinafter "Subcomm. Rep."]. The fragility of supply was shown when the one remaining manufacturer experienced production problems. *Id.* at 69.

This was the "unstable and unpredictable childhood vaccine market" Congress observed. H.R. Rep. at 5, 1986 U.S.C.C.A.N. at 6346. There was "a short term crisis of availability of DTP vaccine."

Subcomm. Rep. at 68. The shortage became so dire that the Centers for Disease Control and Prevention ("CDC") recommended stretching out the vaccination schedule—diluting children's protection. *Id.* at 69.

Congress sounded the alarm: The "withdrawal of even a single [additional] manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps a resurgence of preventable disease." H.R. Rep. at 7, 1986 U.S.C.C.A.N. at 6348.

Congress Averts the Crisis with the Vaccine Act

Congress responded to the public health crisis decisively—by passing the Vaccine Act. The Vaccine Act is an intricate and comprehensive federal scheme to insulate the remaining (and new) vaccine manufacturers from litigation, while both compensating the few individuals who suffer adverse side effects and fostering the development of safer and more effective vaccines.

Shielding vaccine manufacturers from tort litigation. The element of the statutory scheme that protects vaccine manufacturers from the potentially ruinous burden of litigation, which is at the heart of this petition, is Section 22(b)(1). It provides, in full:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was

> properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1). This preemption clause preserves a limited tort remedy against a manufacturer for injuries caused by a vaccine not made according to its FDA-approved formula or that does not provide proper directions and warnings for use.[1] *See* H.R. Rep. at 26, 1986 U.S.C.C.A.N. at 6367 (claimants who "cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should pursue recompense in the [administrative] compensation system, not the tort system."). Such claims, however, did not drive the litigation crisis. The question in this case is whether the reference to "unavoidable" injuries somehow leaves open the possibility of liability for design defect claims—the very sorts of claims that were central to the litigation in the 1980s.

Whatever the answer to this question, *any* claim for a vaccine-related injury must begin with a petition for compensation in the Vaccine Court, which is an adjunct to the Court of Federal Claims. 42 U.S.C. §§ 300aa-11(a)(2), 12(c), 21(a). The Secretary of the United States Department of Health and Human Services ("HHS") appears as a respondent: vaccine manufacturers are not parties

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[1] The Vaccine Act allows a presumption that FDA-approved directions and warnings are adequate. 42 U.S.C. § 300aa-22(b)(2). That provision, and the scope of its effect upon failure-to-warn claims, is not at issue in this petition.

to Vaccine Court litigation. *See id.* § 300aa-12(b). Compensation, paid out of the proceeds from a vaccine tax, is awarded on a no-fault basis. *Id.* §§ 300aa-13, 14, 15(i). A Vaccine Court claimant need not prove that the vaccine was in any way defective or that the injury could have been avoided through a safer design or otherwise—as tort law would require—but only that there is a causal link between the injury and the vaccine. *See id.* § 300aa-13. Congress designed this mandatory federal remedy "to work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995).

For vaccine-related injury claims preempted by Section 22(b), the Vaccine Court remedy (with its attendant appeals) is the only remedy available. For those vaccine-related injury claims that may be pursued in a civil action, the claimant who exhausts the Vaccine Court process has a choice to make: accept the Vaccine Court's judgment, or elect against it and litigate from square one in court, subject to several substantive and procedural constraints. *See* 42 U.S.C. § 300aa-21.

The National Vaccine Program. The Vaccine Act also established a National Vaccine Program to "promote the development of childhood vaccines that result in fewer and less serious adverse reactions," and to "assure improvements in . . . the licensing, manufacturing, processing, testing, labeling, warning, . . . and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." *Id.* § 300aa-27(a)(1)-(2). Through this program, lodged in HHS, nearly a dozen federal agencies ("NVP Agencies") collaborate "to achieve optimal

prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." *Id.* §§ 300aa-1, 2; HHS/Public Health Service/National Vaccine Program Office, *The U.S. National Vaccine Plan – 1994*, at 3 (1994) (listing responsibilities of various agencies).

One of the key agencies in the program is the FDA, which regulates the formulation, production, and labeling of childhood vaccines. *See* 21 U.S.C. § 301 *et seq.*; 42 U.S.C. § 262(c); 21 C.F.R. § 600 *et seq.* An FDA-licensed vaccine must be made according to its approved formula. *See* 21 C.F.R. §§ 601.2, 601.12. The FDA "makes approval decisions based not on abstract estimation of [a prescription product's] safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). The FDA strikes the delicate balance between safety and efficacy, ever aware that any vaccine inevitably causes some adverse reactions and that making a vaccine safer can sometimes compromise its efficacy. *Cf. Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) (describing FDA's balancing of medical device's costs and benefits). Even after approval, the FDA, the CDC, and the National Institutes of Health all monitor safety data from the vaccine manufacturers and several independent sources. *See* 42 U.S.C. § 300aa-2(a)(2)-(3).

Trial Court Dismisses Plaintiffs' Design Defect Claims

Respondents (referred to here as "plaintiffs") are the parents of an autistic child. They claim that FDA-approved vaccines caused their child's autism—pinning the blame specifically on thimerosal, the preservative used in the FDA-approved formulations. While allegations of this sort have swept through the media and the internet, every reputable scientific body and governmental agency that has studied the question—including the FDA and CDC—has rejected any linkage between vaccines and autism. *See, e.g.*, FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/cber/vaccine/thimerosal.htm. (last modified Jan. 14, 2009) (stating that FDA "conducted a comprehensive review of the use of thimerosal in childhood vaccines," and concluding that there was "no evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity reactions"); CDC, *Mercury and Vaccines (Thimerosal)*, http://www.cdc.gov/vaccinesafety/concerns/thimerosal.htm (last modified Feb. 8, 2008) ("There is no convincing scientific evidence of harm caused by the low doses of thimerosal in vaccines, except for minor effects like redness and swelling at the injection site.").

Most notable and comprehensive among the scientific reviews was the report of a panel of world-renowned experts appointed by the National Academy of Science's Institute of Medicine, which decisively declared that "**the evidence favors rejection of a causal relationship between thimerosal containing vaccines and autism.**"

Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* 7 (2004) (emphasis in original).

Plaintiffs presented their claim to the Vaccine Court, which had already instituted an Omnibus Autism Proceeding. The omnibus proceeding will decide—for some 4,900 like claims—whether there is a causal link between childhood vaccines and autism. On February 12, 2009, the Vaccine Court issued opinions in three test cases considering claimants' theory that the Measles-Mump-Rubella ("MMR") vaccine, in combination with thimerosal-containing vaccines, could cause autism. *See Cedillo v. Sec'y of HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009); *Hazlehurst v. Sec'y of HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009); *Snyder v. Sec'y of HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009). In nearly 700 pages of detailed analysis, the Vaccine Court rejected that theory. The Vaccine Court is expected to issue causation rulings later this year in test cases considering claimants' theory that thimerosal-containing vaccines *alone* could cause autism.

Rather than await a ruling on the merits in the omnibus proceeding, plaintiffs here invoked a provision of the Vaccine Act authorizing them to opt out of Vaccine Court and file a lawsuit in court if the Vaccine Court does not resolve the petition within 240 days. *See* 42 U.S.C. § 300aa-21(b)(1). Plaintiffs sued the vaccine manufacturers (Petitioners here) in state court in Georgia. They asserted claims for strict liability, negligence, fraud, negligent misrepresentation, and breach of warranty. App. 36.

As relevant here, their central theory of liability is design defect—that the FDA-approved designs for the vaccines administered are defective, and the manufacturers should not have used the thimerosal preservative as approved by the FDA.

The vaccine manufacturers moved for summary judgment on the basis that the Vaccine Act preempted plaintiffs' claims. App. 34-35. The trial court entered summary judgment, dismissing the design defect claims. The court reasoned that "Congress [did not] leave vaccine design standards open to reexamination under the laws of each state, with the potential for interstate conflict: the Vaccine Act sets one rule, applicable nationwide, that preempts design defect claims." App. 45. This ruling was consistent with the conclusions other courts had reached on the preemption of vaccine design defect claims. App. 43. The trial court denied summary judgment on the other claims. App. 55.

Georgia Appellate Courts Reverse

The Georgia Court of Appeals reversed. The court acknowledged that "when the contemporaneous legislative history of the Vaccine Act is examined, Congress's intent to preempt [design defect claims] becomes clear." App. 30. Nevertheless, the court felt compelled to disregard congressional intent because it found it could interpret the statutory language in two competing ways: (1) the statute preempts all design defect claims; or (2) design defect claims are preempted "only if the side effects are determined to be unavoidable on a case-by-case basis." App. 29-30. The Court of Appeals believed that this Court's

decision in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), obliged it "to accept the reading of an express preemption statute that disfavors preemption," and to focus on "the statutory language alone," without regard to structure, purpose, or legislative history. App. 28. The court observed that its denial of preemption "is anomalous given the clear legislative history to the contrary, but we are constrained to follow the Supreme Court's explicit guidance in *Bates*." App. 31.

The Georgia Supreme Court granted the vaccine manufacturers' petition to review the Court of Appeals' ruling that the Vaccine Act did not categorically preempt plaintiffs' design defect claims. App. 3. The Georgia Supreme Court rejected the Court of Appeals' logic—specifically, its peculiar reading of *Bates*—but upheld the result on different grounds. App. 3-4. It held that even in light of the Vaccine Act's structure and legislative history, there was no "clear and manifest congressional purpose" to preempt all design defect claims. App. 18.

The Georgia Supreme Court recognized that its ruling conflicted with all of the other courts to have decided the issue (except the Georgia Court of Appeals). App. 7. But it staked out that position for Georgia, "at least until the Supreme Court of the United States has spoken on the issue." App. 18.

REASONS FOR GRANTING THE PETITION

This case presents a stark choice between two rules. Outside of Georgia, courts have ruled that Congress categorically preempted all state-law claims asserting that the manufacturer should have

adopted a vaccine design that was safer than the one the FDA approved. Properly interpreting Section 22(b)(1), these courts have uniformly allowed only suits based on the theory that the vaccine was improperly prepared or labeled. The Georgia Supreme Court reached the opposite conclusion. It held that Congress preempted tort suits only if the manufacturer demonstrates factually, in the specific case presented, that there was *no safer design* that could have avoided the injuries at issue. According to the Georgia Supreme Court, the express preemption clause does not eliminate the need for discovery and trial because Congress intended to leave expert regulatory determinations about vaccine design open to jury re-examination.

In so holding, the court also did violence to the complex and interrelated purposes and structure of the Vaccine Act. It effectively eliminated one of the most important benefits of the Vaccine Act bargain to vaccine companies by subjecting them once again to costly litigation over matters of vaccine safety that Congress has entrusted to federal health agencies. There is no protection from litigation cost if preemption occurs only at the end of discovery and trial when a jury finds, in a specific case applying state law, that the vaccine had the safest possible design for the injury at issue.

As is demonstrated more fully below, the differences between these two judicial interpretations could not be starker, and the conflict is entrenched and intractable—which is reason alone to grant certiorari. *See infra* Point II. But the main reason to grant certiorari is that the choice between the two approaches is a matter of profound national

importance. *See infra* Point I. The Georgia Supreme Court's approach is so demonstrably wrong, *see infra* Point III, and the threat to public health is so real and imminent, that the issue must be resolved now, without further percolation.

I. THIS CASE IS OF PROFOUND NATIONAL IMPORTANCE BECAUSE THE GEORGIA SUPREME COURT'S RULING UNDERCUTS CONGRESS'S LIMITS ON CIVIL LIABILITY AND THREATENS THE NATION'S VACCINE SUPPLY.

The Court should grant this petition because the Georgia Supreme Court's rule threatens public health by inviting a litigation deluge even bigger than the one that spurred Congress to urgent action in 1986. It does not take any imagination to foresee the consequences. First, as in 1986, the Georgia rule will de-stabilize the vaccine market, which could lead to potentially devastating vaccine shortages. Second, it could stall the development of new life-saving vaccines.

The threat to the vaccine supply. The litigation surge that Congress averted in 1986 was nothing compared to the tidal wave that the Georgia Supreme Court's ruling invites. The graph on page 21 shows how many cases it takes to make a crisis. In 1986, when vaccine litigation peaked, plaintiffs were filing hundreds of cases a year. Over 250 of the cases then pending related to the DTP vaccine. Geoffrey Evans, *Update on Vaccine Liability in the*

United States, 42 Clinical Infectious Diseases S130, S134 (2006). [2]

The costs of defending these hundreds of lawsuits were crushing, and increasing. *See* Subcomm. Rep. at 87; H.R. Rep. at 6, 1986 U.S.C.C.A.N. at 6347. Potential liability also loomed over the industry. In 1984, one major vaccine manufacturer (a corporate ancestor of Petitioner Wyeth) estimated that its potential liability from DTP vaccine lawsuits was 200 times its annual sales for the vaccine. Subcomm. Rep. at 69. The litigation costs and potential liability spawned real-world consequences: an unstable and constricted vaccine supply.

The Vaccine Act dramatically altered the litigation status quo through the preemption of certain tort claims and the no-fault compensation program. In just two decades, the compensation fund has awarded more than $1.8 billion to over 2,200 families and individuals. HHS, *HRSA Awards Contract to Study Adverse Events in Childhood Vaccines* (Oct. 23, 2008), http://newsroom.hrsa.gov/releases/2008/vaccinestudy.htm. As the graph on page 21 illustrates, litigation against DTP manufacturers slowed to a trickle after the law took effect. The same is true for cases involving other vaccines. *See id.* The post-Vaccine Act litigation that has been filed to date has been less costly. No case governed by the Vaccine Act against a vaccine manufacturer has proceeded to trial – much less to

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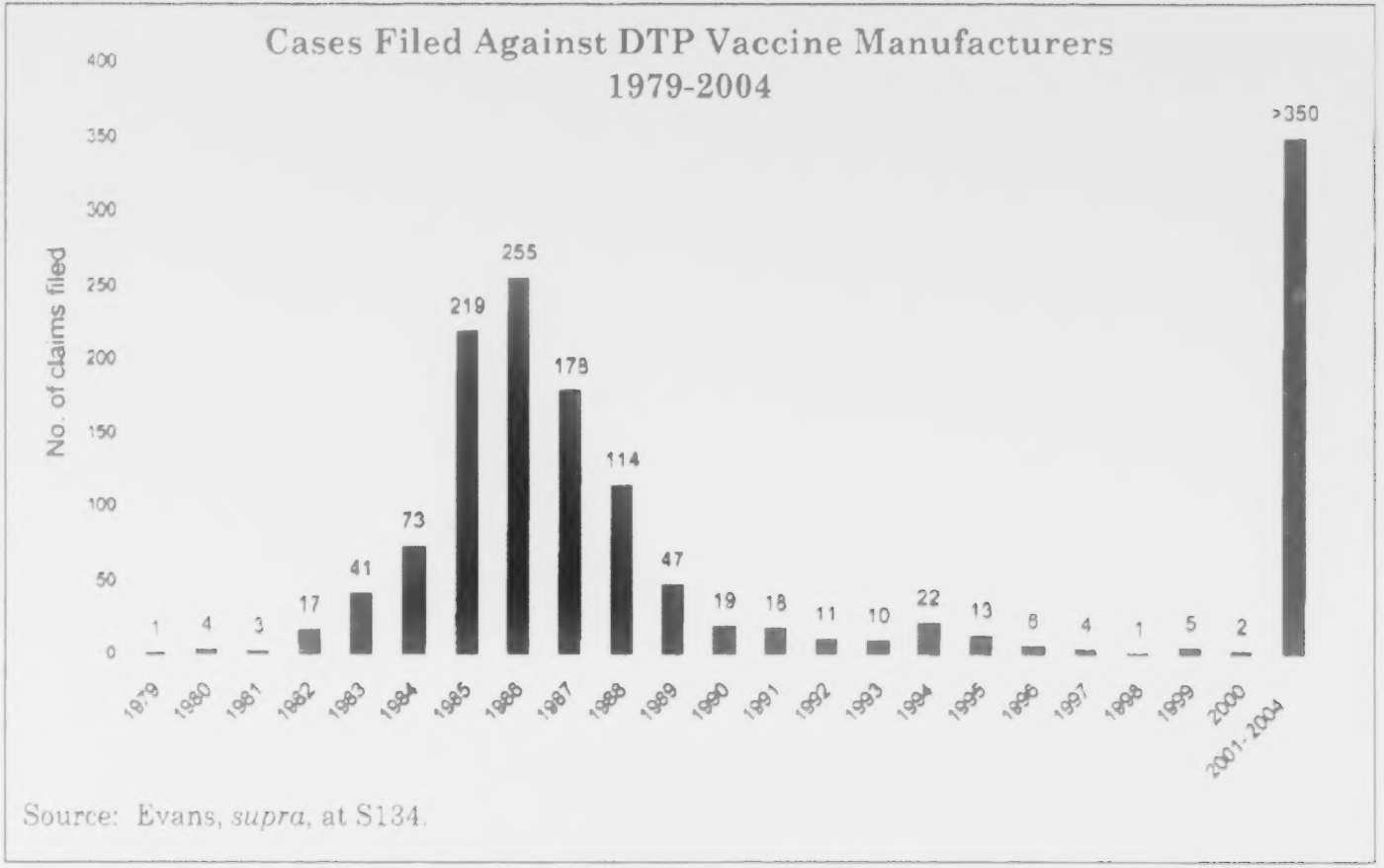
[2] For the most part, the DTP lawsuits alleged that the vaccine's design was defective because the pertussis component caused permanent neurological damage.



Source: Evans, *supra*, at S134.

verdict—in the two decades since the Vaccine Act became effective.

Since 2001, however, plaintiffs have increasingly tested what seemed to be settled limits on litigation. Civil suits against vaccine manufacturers are up again. The filings now number over 350. Evans, *supra*, at S134. Some of these suits involve multiple plaintiffs. Almost all of these suits include clones of this design defect claim. In Georgia alone, more than 20 cases like this one are pending, and Georgia's rule may attract even more suits against vaccine manufacturers.

Nationwide filings are also bound to spike, as plaintiffs, emboldened by the Georgia ruling, try to replicate the results in other states. The Vaccine Court's February 12 rulings rejecting claimants' general causation theory in MMR-thimerosal combined cases (*supra* p. 15) foreshadows a denial of Vaccine Act compensation to those claimants and also to those that cite only thimerosal-containing vaccines as the cause of their injuries. A civil action will be their next and only remaining—avenue for relief. If any significant portion of the 4,900 vaccine-autism claimants in Vaccine Court exercise their statutory right to reject that court's judgment and file a civil action, hundreds or even thousands of new vaccine cases will flood the courts. The numbers could easily overtop the level of filings in 1986. Without the categorical preemption of vaccine design claims as intended by Congress, Vaccine Court could be reduced to a mere checkpoint plaintiffs pass through on their way to civil court.

As was true in 1986, the most immediate concern is not the potential liability, but the cost of defending hundreds or thousands of lawsuits. Even if judges and juries eventually accept the prevailing scientific view that vaccines do not cause autism (*see supra* pp. 14-15), the litigation expense will be even more crushing than it was back in 1986. To reach the stage in a litigation at which the discredited causation hypothesis could be challenged, a vaccine manufacturer would have to endure expensive discovery—thousands of times over if the deluge materializes.

This deluge could lead to the very same dangerous situation that existed in the mid-1980s—vaccine manufacturers abandoning the market, which in turn yields vaccine shortages and exposes the nation to the renewed threat of an epidemic. The number of vaccine manufacturers has not increased. In the United States market today, as in 1986, there is still just one manufacturer for the polio vaccine, one for MMR, and two for the DTP vaccine. *Compare* H.R. Rep. at 7, 1986 U.S.C.C.A.N. at 6348, *with* FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/CBER/vaccine/thimerosal.htm (last modified Jan. 14, 2009). The concerns that motivated Congress in 1986 would reappear: The loss of even one more vaccine manufacturer "could create a genuine public health hazard." H.R. Rep. at 7, 1986 U.S.C.C.A.N. at 6348. The same concerns that compelled Congress to intervene and pass the Vaccine Act in the first place, should compel the Court to intervene and verify which interpretation of the Act is correct—the one that has fulfilled Congress's goal in achieving vaccine stability or the

one that will revive the crisis Congress averted over two decades ago.

The threat to vaccine development. While the Congress that passed the Vaccine Act was most urgently concerned about the public health consequences of the litigation crisis, it recognized the need for vigilance in developing new vaccines and improving existing ones. Congress noticed that vaccine manufacturers were limiting their investment in research and development for two primary reasons. First, the cost of developing a new vaccine is prohibitive: The investment could be as much as 30% of the industry's total annual sales. Subcomm. Rep. at 72. Second, the staggering potential tort liability for vaccine-related injury claims, notwithstanding an FDA-approved vaccine design, could easily lead a drug manufacturer to conclude the investment is not worth the price. *Id.*

While Congress directed several federal agencies to supplement the vaccine research being conducted by the industry, Congress understood that efforts would fail unless the agencies collaborated closely with the industry. *See* H.R. Rep. at 11, 1986 U.S.C.C.A.N. at 6352. The public-private collaboration Congress envisioned has had astounding success. Since 1986, the collaboration has yielded seven new vaccines now on the routine childhood immunization schedule: hepatitis B; varicella; pneumococcal disease; influenza; hepatitis A; meningococcal disease; and rotavirus. *Compare* CDC, *Recommendation of the Immunization Practices Advisory Committee New Recommended Schedule for Active Immunization of Normal Infants and Children*, 35 MMWR 577 (Sep. 19, 1986), *with*

CDC, *Recommended Immunization Schedules for Persons Aged 0-18 Years—United States, 2008*, 57 MMWR Q1 (Jan. 11, 2008).

All three of the vaccines being challenged in this case were products of the National Vaccine Program. Among them is Wyeth's vaccine for *Haemophilus influenzae* type B ("Hib"), which is an especially good illustration of the Program's success. Hib—the leading cause of childhood bacterial meningitis and postnatal mental retardation—formerly afflicted some 20,000 children a year. *See* CDC, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MMWR 241, 246 (Apr. 2, 1999). In the decade after Wyeth introduced its vaccine for infants, the incidence of Hib invasive disease in children under five fell 99%. *See* Kashif Iqbal et al., *Haemophilus influenzae Type b Invasive Disease*, 2-1 (2008), http://www.cdc.gov/vaccines/pubs/surv-manual/chpt02-hib.pdf.

The work on vaccines is far from over. The need remains for improvement and invention. To take one example, current influenza and pneumococcal vaccines must be adapted to battle new strains of the disease. *See* Laura Beil, *Worrisome Infection Eludes a Leading Children's Vaccine*, N.Y. Times, Oct. 14, 2008. Beyond the diseases that currently afflict our population, public health authorities must guard against foreign invaders. A single peripatetic host carrying a foreign disease could spark an epidemic here, just as a Severe Acute Respiratory Syndrome ("SARS") epidemic spread from China to 37 countries in a matter of weeks. *See* Richard D. Smith, *Responding to Global Infectious Disease Outbreaks: Lessons from SARS on the Role of Risk Perception*,

Communication and Management, 63 Soc. Sci. & Med. 3113 (2006). A robust research program that explores new vaccines is our best protection from these intruders.

Congress worried that a wave of product liability litigation would deter investment in new or improved vaccines and undermine collaboration with federal agencies. That same concern is equally real now. Once again, the choice is as grave as it is clear: a legal rule that will extend the collaborative vaccine success over the past two decades versus the Georgia rule, which will encourage the pharmaceutical industry to withdraw from vaccine research.

II. THE SPLIT OVER WHETHER THE VACCINE ACT CATEGORICALLY PREEMPTS ALL DESIGN DEFECT CLAIMS IS ACKNOWLEDGED AND INTRACTABLE.

The conflict between the Georgia Supreme Court and the majority rule is stark, acknowledged, and intractable.

All courts outside of Georgia that have ruled on the issue have held that the Vaccine Act's preemption clause expressly preempts all design defect claims. *See Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845-46 (Sup. Ct. 2003), *aff'd*, 810 N.Y.S.2d 506 (App. Div. 2006), *leave denied*, 857 N.E.2d 1137 (N.Y. 2006) (table); *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 444-46 (E.D. Pa. 2007), *appeal docketed*, No. 07-3794 (3d Cir. argued Sep. 11, 2008); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 299-303 (E.D. Pa. 2007); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664-66

(S.D. Tex. 2004); *Wright v. Aventis Pasteur, Inc.*, No. 3861, 2008 WL 4144386 (Pa. Ct. Com. Pl. Aug. 27, 2008), *appeal docketed*, No. 336 EDA 2008 (Pa. Super. Ct.). These courts have concluded that the Vaccine Act expressly preempts all liability of vaccine manufacturers unless the claimed injury could have been avoided by proper preparation or proper directions and warnings. "If the alleged defect that caused the claimant's injury does not fall into one of [those] two enumerated categories, the defect is considered 'unavoidable,' and the claimant's tort claim is barred." *Blackmon*, 328 F. Supp. 2d at 664.[3] These courts reach this conclusion as a matter of plain language, legislative history, and statutory structure.

The Georgia Supreme Court reached the opposite conclusion when it held that the Vaccine Act's preemption clause "clearly does not preempt all design defect claims against vaccine manufacturers," App. 15, "but instead provides that a vaccine manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the injurious side effects of the particular

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[3] This Court's recent decision in *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172 (U.S. Mar. 4, 2009), is not relevant to the question presented by this petition. The Court held in *Levine* that the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, did not impliedly preempt plaintiff's failure-to-warn claim relating to the prescription drug Phenergan. *Id.* at *13. The question presented by this petition, however, is whether Congress intended for 42 U.S.C. § 300aa-22(b)(1) of the Vaccine Act to expressly preempt all design defect claims for childhood vaccines.

vaccine were unavoidable." App. 4. In so holding, the Georgia Supreme Court cited and analyzed the cases in the majority camp, but found them "erroneous[]" and "mistaken[]" on each point—statutory language, legislative history, and structure. App. 8-12, 16-18.

In short, courts presented with the same tort claims, the same statute, and the same legislative history have come to diametrically opposite conclusions. The conflict is entrenched and acknowledged, and the Georgia Supreme Court has declared that its decision would remain the law of Georgia "at least until the Supreme Court of the United States has spoken on the issue." App. 18. Until then, vaccine manufacturers sued in Georgia (or in other states that may follow Georgia's lead) will not have the benefit of the preemption defense—and the conflict among the lower courts will remain.

Admittedly, the conflict presented here has not ripened to the level this Court typically prefers—a conflict between a state's highest court and a federal court of appeals—at least not at this moment. The preferred sort of conflict may well materialize while this petition is pending. The Third Circuit is poised to issue an opinion on the issue presented here, as it is now reviewing a district court opinion holding that the Vaccine Act categorically preempts all design defect claims. *See Bruesewitz*, 508 F. Supp. 2d at 446, *appeal docketed*, No. 07-3794 (3d Cir.). The Third Circuit heard argument in mid-September, 2008, and its opinion is imminent.

In any event, for reasons already described, *see supra* Point I, the issue warrants this Court's

immediate attention. Neither Petitioners nor the public have the luxury to allow the issue to percolate further, because the Georgia Supreme Court's position will precipitate a litigation deluge that will threaten public health.

III. THE GEORGIA SUPREME COURT ERRED IN HOLDING THAT THE VACCINE ACT DOES NOT PREEMPT ALL DESIGN DEFECT CLAIMS.

Review is also warranted because the Georgia Supreme Court erred at every step of its analysis—on its construction of the language of the preemption provision, the legislative history, and the structure of the Vaccine Act. The Court read the statute in a truncated fashion, improperly fixating upon Section 22(b)(1)'s language about "side effects that were unavoidable" and disregarding the remainder of the sentence. By ignoring those words, it arrived at a construction that betrayed Congress's intent that a side effect from an FDA-approved vaccine be considered "unavoidable" *as long as* "the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). In other words, the provision immunizes vaccine manufacturers from *all* liability in any civil action for vaccine-related injury regardless of legal theory, unless the injury at issue could have been avoided by proper preparation or "proper directions and warnings"—with the proviso that directions and warnings are ordinarily presumed to be "proper" if they were FDA approved. 42 U.S.C. § 300aa-22(b)(2).

Like the other courts to address the issue, the Georgia Supreme Court recognized that Section 22(b)(1)'s language derives from the well-known Comment k to Section 402(A) of the Restatement (Second) of Torts. App. 7. Comment k protects a certain class of products from strict liability: products deemed to be "unavoidably unsafe" because they carry an inherent risk of injury. Restatement (Second) of Torts § 402A cmt. k. While various states have taken different paths to determining whether products are entitled to the protection of Comment k, the Georgia Supreme Court erred in failing to recognize that Congress made the blanket determination that childhood vaccines are "unavoidably unsafe" and should be categorically exempt from liability for injuries resulting from inherent risks. *See* H.R. Rep. at 26, 1986 U.S.C.C.A.N. at 6367 (stating that the principle of Comment k "appl[ies] to the vaccines covered in the [Act] and that such products not be the subject of liability in the tort system").

As to legislative history, the courts adhering to the majority view—and even the Georgia Court of Appeals, App. 30—have correctly pointed out that congressional intent could not be clearer. The legislative history "indicates rather clearly the Committee's intent to relegate design defect claims to the [Vaccine Court] compensation system." *Blackmon*, 328 F. Supp. 2d at 665; *see also Militrano*, 810 N.Y.S.2d at 508 (holding that the "Committee's discussion of the issue clearly establishes Congress' determination that the Comment k defense bars all [vaccine design defect] claims"). The key committee report explains:

> Given the existence of the compensation system in [the Vaccine Act], the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was *improperly prepared* or that it was *accompanied by improper directions or inadequate warnings* [they] *should pursue recompense in the compensation system, not the tort system.*

H.R. Rep. at 26, 1986 U.S.C.C.A.N. at 6367 (emphasis added).

The Georgia Supreme Court erred in relying instead on a post-enactment legislative statement that other courts correctly ignored. *See* App. 13-14. Such subsequent legislative history is "a 'hazardous basis for inferring the intent of an earlier' Congress." *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)). That cautionary note is especially apt here. The 1987 committee report on which the court relied to discern Congress's intent a year earlier related to the funding of the Act. The funding amendments had nothing to do with the preemption clause's limitations on liability that govern post-Vaccine Court civil actions.

Perhaps the Georgia Supreme Court's most fundamental error, however, was to ignore the statutory structure and context for Section 22. The

Georgia Supreme Court declared, without any elaboration, that its analysis was "consistent with the structure and purpose of the Vaccine Act." App. 15 (citation omitted). In fact, the decision is at war with the Act's structure and purpose. While the Georgia Supreme Court's ruling assumes that permitting litigation over vaccine designs would lead to safer vaccines, *see* App. 17, Congress chose a very different policy. Congress saw the consequences of leaving vaccine injury litigation to a tort regime like the one the Georgia Supreme Court adopted here: a dangerously unstable vaccine market and the constant threat of a public health crisis.

The Georgia Supreme Court overlooked the perfect symmetry between a single federal standard for vaccine design and the Vaccine Act's complementary components. Congress commits the controlling evaluation of vaccine design to the FDA, with the input, monitoring, and enhancement of other NVP Agencies. This decision to empower a network of federal agencies to strike the optimum balance between safety and efficacy complements the decision to allow any person injured by a vaccine approved for nationwide use to seek no-fault compensation in the Vaccine Court, without having to prove (as state tort-law would require) that the safety-efficacy trade-off was unreasonable. With that uncommonly generous compensation program in place, Congress preempted tort litigation premised on the view that the vaccine that the FDA approved, and the other NVP Agencies vetted and monitored, should have been safer.

When Congress created this comprehensive scheme, it left no role for juries in 50 disparate state

tort regimes to second-guess the safety of a vaccine's approved design. Inconsistent determinations of the "safest" vaccine design by courts in different states would undermine the NVP Agencies' central role in combating the spread of infectious diseases. As this Court recognized just last Term, "[s]tate tort law that requires a manufacturer's [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Riegel*, 128 S. Ct. at 1008. For reasons discussed above, this admonition is even truer for vaccines.

With the comprehensive and integrated program created by the Vaccine Act, Congress averted the public health crisis in 1986. This Court should grant this petition to review an opinion that invites the public health crisis back.

CONCLUSION

For the foregoing reasons, this Court should grant a writ of certiorari to review the judgment of the Supreme Court of Georgia.

Respectfully submitted.

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APPENDICES

APPENDIX A

SUPREME COURT OF GEORGIA

AMERICAN HOME PRODUCTS CORPORATION et al.
v.
FERRARI et al.

No. S07G1708.

Oct. 6, 2008.

CARLEY, Justice.

Appellees Marcelo and Carolyn Ferrari, individually and on behalf of their minor son, brought suit against several vaccine manufacturers, including Appellants, alleging that their son suffered neurological damage caused by vaccines made with the preservative thimerosal, which contained the toxic substance mercury. Appellees' claims under Georgia law included strict liability and negligence. They specifically alleged that Appellants could and should have manufactured children's vaccines without thimerosal before Appellees' son was vaccinated in 1998.

The trial court granted partial summary judgment in favor of Appellants, ruling that Appellees' design defect claims were preempted by the National Childhood Vaccine Injury Compensation Act of 1986, 42 U.S.C. § 300aa-1 et seq. (Vaccine Act). Section 300aa-22 (b)(1) of the Vaccine Act reads as follows:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

On appeal, the Court of Appeals summarized the parties' arguments as follows:

> [Appellants] argue that the Vaccine Act bars [Appellees'] design defect claims because "any vaccine-related injury would be deemed 'unavoidable' if the vaccine was properly prepared and accompanied by proper warnings." [Cit.] [Appellants] essentially equate FDA [Food and Drug Administration] approval with a determination that side effects are "unavoidable." [Cit.] [Appellees], on the other hand, assert that design defect claims are barred only if the side effects are determined on a case-by-case basis to be "unavoidable." They argue that their child's injuries could have been avoided if the defendants had used a mercury-free preservative for multi-dose vials of their vaccines or if they had simply manufactured single-dose vials that did not require a preservative.

Ferrari v. American Home Products Corp., 286 Ga. App. 305, 308, 650 S.E.2d 585 (2007). The Court of

Appeals determined that two alternative readings of 42 U.S.C. § 300aa-22 (b)(1) exist:

> One reading is that vaccine injuries are "unavoidable" and subject to preemption if the vaccine was properly prepared and accompanied by proper directions and warnings. The other reading is that design defect claims are preempted only if the side effects are determined to be unavoidable on a case-by-case basis.

Ferrari v. American Home Products Corp., supra at 311, 650 S.E.2d 585. The Court of Appeals held that, despite clear legislative history favoring the first reading, *Bates v. Dow Agrosciences*, 544 U.S. 431, 449(III), 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005) imposes

> "a duty to accept the reading (of the Vaccine Act) that disfavors pre-emption," and we cannot resort to an examination of legislative history to discern Congress's intent. [Cit.] Because two plausible, alternative readings of the Vaccine Act exist, we must conclude that the trial court erred by finding that [Appellees'] design defect claims are preempted.

Ferrari v. American Home Products Corp., supra at 312(1), 650 S.E.2d 585. We granted certiorari to consider this ruling. Although the Court of Appeals erred in holding that *Bates* precludes the use of legislative history, we nevertheless affirm the judgment of the Court of Appeals because a full

examination of both the text of 42 U.S.C. § 300aa-22 (b)(1) and the congressional intent behind it shows that the Vaccine Act does not preempt all design defect claims, but instead provides that a vaccine manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the injurious side effects of the particular vaccine were unavoidable.

1. "Except as provided in subsections (b), (c), and (e) [of § 300aa-22] State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22 (a). Thus, in construing subsection (b)(1), "we are presented with the task of interpreting a statutory provision that expressly pre-empts state law." *Medtronic v. Lohr*, 518 U.S. 470, 484(III), 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996). Although this subsection "preempts state law to the extent stated, the [Vaccine] Act, by expressly reserving state courts a role with respect to claims made under the Act, does not preclude state courts from adjudicating issues raised regarding it ([cit.])." *Militrano v. Lederle Laboratories*, 3 Misc. 3d 523, 769 N.Y.S.2d 839, 843 (2003), aff'd, 26 A.D.3d 475, 810 N.Y.S.2d 506 (App. Div. 2006).

While the language of subsection (b)(1) indicates that Congress intended to preempt some state law, we are nonetheless required to

> "identify the domain expressly pre empted" by that language, [cit.] Although our analysis of the scope of the pre-emption statute must begin with its text, [cit.], our

interpretation of that language does not occur in a contextual vacuum. Rather, that interpretation is informed by two presumptions about the nature of pre-emption. [Cit.] First, because the States are independent sovereigns in our federal system, . . . Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," [cit.], we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." [Cits.] . . . [T]his assumption should apply . . . to questions concerning the *scope* of its intended invalidation of state law, [cit.] . . . That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety. Second, our analysis of the scope of the statute's pre-emption is guided by [the] oft-repeated comment . . . that "(t)he purpose of Congress is the ultimate touchstone" in every pre-emption case. [Cits.] As a result, any understanding of the scope of a pre-emption statute must rest primarily on "a fair understanding of *congressional purpose*." [Cit.] Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the "statutory framework" surrounding it.

> [Cit.] Also relevant, however, is the "structure and purpose of the statute as a whole," [cit.], as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law. (Emphasis in original.)

Medtronic v. Lohr, supra at 484-486(III), 116 S. Ct. 2240 (with five Justices joining this part of the Supreme Court's opinion).

The Court of Appeals viewed *Bates* as having drastically changed this traditional preemption analysis, so as to make the presumption against preemption irrebuttable and to require examination of the statutory language alone. *Ferrari v. American Home Products Corp.*, supra at 310, 650 S.E.2d 585. "However, *Bates* does not require a court to automatically accept a plausible interpretation of a statute which disfavors preemption." *Bruesewitz v. Wyeth*, 508 F. Supp. 2d 430, 444(V)(B)(2)(a) (E.D. Pa. 2007). *Bates* quotes from the above-quoted portion of *Medtronic* which sets forth the presumption against preemption, without any indication of disapproval. Furthermore, "*Bates* itself relies on the congressional intent behind [the statute before it] when applying the rule [disfavoring preemption]. [Cit.]" *Bruesewitz v. Wyeth*, supra. See also *Bates v. Dow Agrosciences*, supra at 452(III), fn. 26, 125 S. Ct. 1788 (examining legislative history).

It therefore appears that the Court of Appeals took "one part of the *Bates* ruling out of its context, and [gave] it broader scope than is appropriate." *Bruesewitz v. Wyeth*, supra. Nevertheless, a majority of seven Justices in *Bates* "gave the most explicit statement yet of the presumption against preemption in a product preemption case" and "fully demonstrated its commitment to the presumption against preemption except in the narrowest of circumstances." J. Eggen, "The Normalization of Product Preemption Doctrine," 57 Ala. L. Rev. 725, 762-763(III)(B) (2006).

2. Only two federal district courts and one state other than Georgia have considered in published opinions whether 42 U.S.C. § 300aa-22 (b)(1) preempts all claims that a vaccine was defectively designed. *Bruesewitz v. Wyeth*, supra; *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297(V)(B) (E.D. Pa. 2007) (same court as *Bruesewitz*); *Blackmon v. American Home Products Corp.*, 328 F. Supp. 2d 659, 662(II)(B) (S.D. Tex. 2004); *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d, supra at 843-846, aff'd, 810 N.Y.S.2d, supra at 508. Each of these cases held that all such claims are preempted. However, every case correctly recognized that Congress modeled subsection (b)(1) after comment k to § 402A of the Restatement (Second) of Torts. "Section 402A is a general section providing for strict products liability." *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d, supra at 844. Comment k excepts from strict liability the seller of

> [u]navoidably unsafe products. There are some products which, in the present state of

> human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many . . . drugs, vaccines, and the like . . . .

Restatement (Second) of Torts § 402A cmt. k. The phrase "properly prepared, and accompanied by proper directions and warning" refers to an absence of manufacturing or warning defects and, thus, comment k distinguishes the three fundamental types of products liability: defects in design, manufacturing, and packaging or marketing. *Sykes v. Glaxo-SmithKline*, supra at 300(V)(B)(3); *Blackmon v. American Home Products Corp.*, supra at 664(II)(B). See also *Banks v. ICI Americas*, 264 Ga. 732, 733(1), 450 S.E.2d 671 (1994) ("There are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects. [Cit.]").

However, both *Sykes* and *Blackmon* erroneously construed comment k to support its interpretation of 42 U.S.C. § 300aa-22 (b)(1) as rejecting a case-by-case determination of whether a certain side effect was unavoidable. In particular, *Sykes v. Glaxo-SmithKline*, supra at 302(V)(B)(4), mistakenly held that such interpretation "mirrors this established area of tort law for unavoidably unsafe products" as set forth in comment k. "Comment k., however, has been interpreted in a variety of ways . . ., and there

has been a wide range of disagreement regarding its application." *Freeman v. Hoffman-La Roche*, 260 Neb. 552, 618 N.W.2d 827, 835(IV)(1)(a)(ii) (2000). Only a few jurisdictions have held that any prescription drug is deemed unavoidably unsafe and, thus, that strict liability for defective design is barred. *Freeman v. Hoffman-La Roche*, supra at 836(IV)(1)(a)(ii); *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d, supra at 846. Most of the states, including Georgia, "that have adopted Comment k have applied it in a more limited fashion and on a case-by-case basis. [Cits.]" *Bryant v. Hoffmann-La Roche*, 262 Ga. App. 401, 404(2), 585 S.E.2d 723 (2003) (physical precedent, with one judge urging adoption of a design defect test in the Restatement (Third) of Torts, which test was neither adopted by Congress in the Vaccine Act nor in existence at the time). Indeed, even *Bruesewitz* understands comment k in this manner:

> Comment k, therefore, suggests that the question of whether a particular vaccine is unavoidably unsafe-and therefore subject to the immunity from suit posited by comment k-is a question of fact for a jury to determine. That is, the trier of fact must decide whether the challenged vaccine is the only design available, "in the present state of human knowledge."

Bruesewitz v. Wyeth, supra at 445(V)(B)(3). Thus, the court in *Bruesewitz*, despite its adherence to *Sykes* "ultimate holding, was compelled to acknowledge *Sykes*" misunderstanding of comment k. *Bruesewitz v. Wyeth*, supra at 445-446(V)(B)(3)

("conclud[ing] that § 22(b) is broader than comment k").

3. An analysis of the language and intent of 42 U.S.C. § 300aa-22 (b)(1), unhindered by the mistakes of *Blackmon* and *Sykes*, shows that Congress not only adopted comment k, but understood that comment in the same way that *Bruesewitz* and the great majority of other courts came to understand it. Subsection (b)(1) borrows liberally from the language of comment k, and the committee report on which *Blackmon*, *Sykes*, *Bruesewitz*, and *Militrano* rely states, without qualification, that "[t]his provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) . . . ." H.R. Rep. 99-908, at 25 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6366.

The text of subsection (b)(1) is most consistent with the majority understanding of comment k. Under that subsection, a vaccine manufacturer is not civilly liable "if the [vaccine-related] injury or death resulted from side effects that were unavoidable . . . ." The conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable. In order to bar all liability for defective design and to permit liability only for manufacturing and warning defects, Congress could easily have omitted this clause, retained the last clause, and made the bar to civil liability conditional on proper preparation and warnings, so that subsection (b)(1) would simply state that a vaccine manufacturer is not civilly liable "if the vaccine was properly prepared and was

accompanied by proper directions and warnings." Thus, Appellants effectively "favor reading . . . words out of the statute. . . . This amputated version . . . would no doubt have clearly and succinctly commanded the pre-emption of *all* state" tort claims for defective design. (Emphasis in original.) *Bates v. Dow Agrosciences*, supra at 448-449(III), 125 S. Ct. 1788.

As the statute is actually written, however, it is best understood as barring liability only for those side effects which were unavoidable by means other than proper manufacturing and packaging. Conversely, if such effects were avoidable by a feasible alternative design, liability is not completely barred. Accordingly, the last clause of subsection (b)(1) was necessary to ensure that its bar to liability would not apply to the manufacturing and packaging process, but only to side effects which were not avoidable by a safer design.

4. This construction of 42 U.S.C. § 300aa-22 (b)(1) is bolstered by the previously cited 1986 committee report in the following explanation:

> The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding "unavoidably unsafe" products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.

H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. *Militrano v. Lederle Laboratories*, 810 N.Y.S.2d, supra, acknowledges that this wording "appears to leave open the possibility of a design defect claim with respect [to] vaccines covered by the Vaccine Act. . . ." Indeed, that language alone refutes the Court of Appeals' concession that there is "clear legislative history to the contrary. . . ." *Ferrari v. American Home Products Corp.*, supra at 312(1), 650 S.E.2d 585. Subsequent language in the 1986 committee report carries a similar implication, when it recognizes that the Vaccine Act established a "no-fault compensation system," providing an award to vaccine-injured persons "even if the manufacturer has made as safe a vaccine as possible." H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367.

This context must be considered when reading the following sentence on which *Blackmon, Sykes, Bruesewitz, Militrano*, and Appellants rely:

> Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.

H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. This sentence includes both those persons who have been injured by vaccines which were as safely designed as possible and those injured by vaccines for which there was a safer feasible alternative design. Accordingly, the committee report does not

use language which indicates that use of the compensation system is mandatory. The immediately preceding sentence states that "[v]accine-injured persons will now have an appealing alternative to the tort system." H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. Thus, Congress defended the new compensation system by assuming that it would attract even vaccine-injured persons who may be able to prove that the vaccine was not made as safe as reasonably possible. Such an assumption about a no-fault compensation system is certainly questionable, to say the least. However, the assumption is not relevant for its accuracy, but rather for its illumination of congressional intent. Upon considering Congress' assumption regarding the compensation system for that proper purpose, we conclude that the sentence of the committee report on which Appellants rely means only that, in the committee's opinion, if a vaccine-injured person does not have a claim for a manufacturing or warning defect, he should find the compensation system appealing even though he is authorized to attempt to prove the existence of a safer design in the tort system. Accordingly, that sentence does not mean that 42 U.S.C. § 300aa-22 (b)(1) preempts all design defect claims.

The Court of Appeals rejected the use of "subsequent legislative history" as "'a hazardous basis for inferring the intent of an earlier Congress.' [Cit.]" *Ferrari v. American Home Products Corp.*, supra at 311, fn. 9, 650 S.E.2d 585. That subsequent legislative history consists of a report by the same committee which originally considered the Vaccine Act and which produced the 1986 report relied upon

by Appellants and the courts. The subsequent committee report was issued in 1987, the year following passage of the Vaccine Act, and related to amendments to that Act which did become law. In these circumstances, the 1987 committee report is relevant to "shed[ ] light on allegedly ambiguous language" and "certainly constitutes a prophylactic against adopting a tortured reading of an otherwise plain statute." *Grapevine Imports v. United States*, 71 Fed. Cl. 324, 335(II)(C)(3) (2006). That report is strikingly clear and emphatic:

> [T]he codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

H.R. Rep. 100-391(I), at 691 (1987), as reprinted in 1987 U.S.C.C.A.N. 2313-1, 2313-365.

Furthermore, an amendment to the Vaccine Act which would have established "that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act." H.R. Rep. 100-391(I), at 691, 1987 U.S.C.C.A.N. at 2313-365. "Generally the rejection of an amendment indicates that the legislature does not intend the bill to

include the provisions embodied in the rejected amendment. [Cits.]" 2A Sutherland Statutory Construction § 48:18 (7th ed.).

5. Our analysis is consistent with the structure and purpose of the Vaccine Act as a whole, as correctly summarized by the Court of Appeals:

> Congress enacted the Vaccine Act "to prevent manufacturers from leaving vaccine production or significantly increasing their prices, while at the same time compensat(ing) victims of vaccine-related injuries quickly." [Cit.] The Vaccine Act creates a no-fault compensation system for victims of certain vaccine-related injuries and requires injured parties to file a petition in the vaccine court. [Cits.] If the injured party is not satisfied with the outcome of the vaccine court process, he or she may pursue a traditional tort action, subject to certain restrictions imposed by the Vaccine Act. [Cits.]

Ferrari v. American Home Products Corp., supra at 306, 650 S.E.2d 585. Accordingly, we must not "overstate the degree of uniformity and centralization that characterizes" the Vaccine Act. *Bates v. Dow Agrosciences*, supra at 450(III), 125 S. Ct. 1788. Having thoroughly examined both the text of 42 U.S.C. § 300aa-22 (b)(1) and the congressional intent behind that subsection and the entire Act, including the relevant legislative history, we hold that subsection (b)(1) clearly does not preempt all design defect claims against vaccine manufacturers,

but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe.

Even if the language of 42 U.S.C. § 300aa-22 (b)(1) is ambiguous, the legislative history hardly shows a "clear and manifest" congressional purpose to supplant state tort law with respect to claims of defective design. Thus, although the Court of Appeals mistakenly construed *Bates* to preclude reliance on any indication of congressional intent other than the statutory language, *Bates* would nonetheless apply to resolve any ambiguity in subsection (b)(1) against preemption.

> Even if [Appellants] had offered us a plausible alternative reading of [that subsection]-indeed, even if its alternative were just as plausible as our reading of that text-we would nevertheless have a duty to accept the reading that disfavors pre-emption. . . . The long history of tort litigation against manufacturers of [prescription drugs and vaccines] adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly. [Cit.]

Bates v. Dow Agrosciences, supra at 449(III), 125 S. Ct. 1788.

Our holding is not undermined by the "four conclusions" of *Sykes v. Glaxo-SmithKline*, supra at 301-303(V)(B)(4), as utilized in *Bruesewitz v. Wyeth*, supra at 445(V)(B)(3). First, 42 U.S.C. § 300aa-22 (b)(1) does not "protect vaccine manufacturers from suit [for] design defects." *Bruesewitz v. Wyeth*, supra. Rather, it protects them from liability for unavoidable side effects. Second, the federal district court in *Bruesewitz* and *Sykes* failed to explain how the National Vaccine Program set up by the Vaccine Act will better promote the discovery of safer alternative designs if manufacturers are given a blanket tort immunity for design defects. See *Bates v. Dow Agrosciences*, supra at 450(III), 125 S. Ct. 1788; *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d 839 supra (decisions favoring the majority view of comment k "emphasize that blanket immunity from tort liability would remove an incentive for developing safer designs ([cit.])"). Third, as discussed above, the legislative history does not show that Congress intended that the no-fault compensation system would balance the supposed elimination of design defect claims. Fourth, the district court did not cite any authority for its conclusion that FDA approval alone renders a vaccine unavoidably unsafe, and that conclusion is not compatible with the majority interpretation of comment k in the realm of prescription drugs. See *Adams v. G.D. Searle & Co.*, 576 So.2d 728, 733 (Fla. App. 1991) (cited in *Bryant v. Hoffman-La Roche*, supra) ("it seems likely to us that a drug manufacturer is in a better position to monitor the current state of knowledge and technology, as applied to its products, than is the FDA. We

hesitate to hold that a manufacturer is excused from making changes it knows will improve its product merely because an older, more dangerous version received FDA approval. We therefore reject a blanket approach and decline to apply comment k to all prescription products."); Christopher J. Albee & Dawn Kilgallen, Comment, *Providing Blanket Comment K Immunity to All FDA Approved Ethical Drugs: The Defect in Grundberg v. Upjohn Co.*, 7 St. John's J. Legal Comment 475 (1991).

The text of 42 U.S.C. § 300aa-22 (b)(1) is not directed towards any particular cause of action, but rather encompasses products liability claims based upon strict liability as well as negligence. *Bruesewitz v. Wyeth*, supra at 440(V)(B), fn. 4; *Sykes v. Glaxo-SmithKline*, supra at 303(V)(B)(5); *Blackmon v. American Home Products Corp.*, supra at 666(II)(B). Therefore, although the Vaccine Act provides for limited no-fault compensation, construing subsection (b)(1) as set forth in *Bruesewitz*, *Sykes*, *Blackmon*, and *Militrano* "would 'have the perverse effect of granting complete [tort] immunity from design defect liability to an entire industry . . . .' [Cit.]" *Doyle v. Volkswagenwerk Aktiengesellschaft*, 267 Ga. 574, 576-577, 481 S.E.2d 518 (1997) (quoting *Medtronic v. Lohr*, supra at 487(IV), 116 S. Ct. 2240). In the absence of any clear and manifest congressional purpose to achieve that result, we must reject such a far-reaching interpretation of 42 U.S.C. § 300aa-22 (b)(1), at least until the Supreme Court of the United States has spoken on the issue.

Judgment affirmed. All the Justices concur.

APPENDIX B

COURT OF APPEALS OF GEORGIA, FOURTH DIVISION

FERRARI et al. v. AMERICAN HOME PRODUCTS CORPORATION et al.	No. A07A0306.

July 5, 2007.

SMITH, Presiding Judge.

In this case involving an issue of first impression, we are called upon to address whether the National Childhood Vaccine Injury Compensation Act of 1986 ("Vaccine Act"), 42 U.S.C. § 300aa-1 et seq., preempts a lawsuit for injuries allegedly caused by the routine vaccination of a child.[1] The trial court concluded that a portion of the plaintiffs' claims are preempted by the Vaccine Act and granted partial summary judgment in favor of the defendants. For the reasons set forth below, we reverse.

Summary judgment is proper when no genuine issue of material fact appears and the movant is entitled to judgment as a matter of law. OCGA § 9-11-56(c). We review the grant or denial of a motion for summary judgment de novo, construing the evidence and all reasonable inferences in the light

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[1] This appeal does not address the causation element of the plaintiffs' claims.

most favorable to the nonmovant. *Matjoulis v. Integon Gen. Ins. Corp.*, 226 Ga. App. 459(1), 486 S.E.2d 684 (1997). So viewed, the record shows that Marcelo and Carolyn Ferrari, individually and on behalf of their minor son, Stefan Ferrari, sued nine children's vaccine manufacturers ("vaccine defendants"),[2] eight thimerosal manufacturers,[3] and one rhogam manufacturer[4] for alleged neurological damage to their son caused by vaccines containing thimerosal preservative, which in turn contained mercury. According to the Ferraris, their son's neurological damage was caused by the mercury, which is toxic to humans. The Ferraris also sued Georgia Power, claiming that mercury emissions from its power plants also injured their son. The Ferraris asserted claims under Georgia law for strict liability and negligence. The Ferraris alleged the vaccine defendants negligently researched, manufactured, tested or failed to test, warned or failed to warn, and failed to recall thimerosal-containing vaccines. According to the Ferraris, the vaccine defendants could and should have manufactured children's vaccines without thimerosal before their son was vaccinated in 1998.

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[2] Sanofi Pasteur, Inc., Aventis Pharmaceuticals, Inc., SmithKline Beecham Corporation, GlaxoSmithKline, GlaxoSmithKline Biologicals, S.A., GlaxoSmithKline Belgium, Wyeth, Lederle, Inc., and Lederle Pharmaceutical.

[3] Eli Lilly and Company, Inc., Sigma-Aldrich, Inc., Sigma-Aldrich Corporation, Spectrum Laboratory Products, Inc., Meridian Chemical and Equipment, Inc., American International Chemical, Inc., Dolder, Ltd., and Uriach Corporation.

[4] Ortho-Clinical Diagnostics.

SmithKline Beecham Corporation, GlaxoSmithKline Biologicals, S.A., and Wyeth filed answers denying liability and moved for summary judgment in their favor, claiming that the Vaccine Act preempted the Ferraris' claims. The trial court found that the preemption doctrine applied and granted partial summary judgment to the vaccine defendants on the Ferraris' design defect claims, their failure-to-warn claims to the extent that they alleged a failure to warn the plaintiffs or the general public, and their breach of warranty claims to the extent they asserted that the vaccines were defectively designed. On appeal, the Ferraris assert that the trial court erred by: (1) finding that its design defect claims are preempted; and (2) refusing to consider constitutional arguments raised by the Ferraris after the court had orally announced its ruling in favor of the vaccine defendants.

THE VACCINE ACT

In 1986, Congress enacted the Vaccine Act "to prevent manufacturers from leaving vaccine production or significantly increasing their prices, while at the same time compensat[ing] victims of vaccine-related injuries quickly." *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007). The Vaccine Act creates a no-fault compensation system for victims of certain vaccine-related injuries and requires injured parties to file a petition in the vaccine court. Id. at 299-300; see also 42 U.S.C. §§ 300aa-11(a)(2)(A), 300aa-13(a)(1)(A, B). If the injured party is not satisfied with the outcome of the Vaccine Court process, he or she may pursue a traditional tort action, subject to certain restrictions

imposed by the vaccine act. *Sykes*, 484 F. Supp. 2d at 300-301; see also 42 U.S.C. § 300aa-21(a)(1)-(2). These restrictions modify state law as follows:

> (a) General rule. Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> (b) Unavoidable adverse side effects; warnings.
>
> (1) *No vaccine manufacturer shall be liable in a civil action* for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part [effective Oct. 1, 1988] *if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.*
>
> (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.S. §§ 301 et seq.] and section 351 of the Public Health Service Act [42 U.S.C.S. § 262] (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury

or death for which the civil action was brought unless the plaintiff shows-

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2) [42 U.S.C.S. § 300aa-23(d)(2)(A) or (B)], or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings. No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part [effective Oct. 1, 1988] solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction. The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil

> action against such manufacturer for such injury or death.
>
> (e) *Preemption. No State may establish or enforce a law which prohibits an individual from bringing a* civil *action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle [42 U.S.C.S. § § 300aa-10 et seq.].*

(Emphasis supplied.) 42 U.S.C. § 300aa-22. The Vaccine Act also limits the recovery of punitive damages to cases in which

> the manufacturer engaged in . . . (A) fraud or intentional and wrongful withholding of information from the [FDA] during any phase of a proceeding for approval of [a] vaccine . . ., (B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or (C) other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought.

42 U.S.C. § 300aa-23 (d)(2).

These restrictions expressly "convey Congress's intent to supersede, or preempt, state tort law standards and create legal protections that apply in any civil action brought against a vaccine manufacturer." *Skyes*, supra, 484 F. Supp. 2d at

297. As in *Sykes*, the vaccine defendants argue that the Vaccine Act bars the Ferraris' design defect claims because "any vaccine-related injury would be deemed 'unavoidable' if the vaccine was properly prepared and accompanied by proper warnings." Id. at 299. The vaccine defendants essentially equate FDA approval with a determination that side effects are "unavoidable." See id.

The Ferraris, on the other hand, assert that design defect claims are barred only if the side effects are determined on a case-by-case basis to be "unavoidable." They argue that their child's injuries could have been avoided if the defendants had used a mercury-free preservative for multi-dose vials of their vaccines or if they had simply manufactured single-dose vials that did not require a preservative.

JUDICIAL INTERPRETATION OF SCOPE OF VACCINE ACT PREEMPTION

Only a handful of courts have addressed the scope of the preemption clause found in 42 U.S.C. § 300aa-22, and each has concluded, after examining the legislative history of the Vaccine Act, that the issue of whether side effects are "unavoidable" cannot be litigated in civil actions. See *Sykes*, supra, 484 F. Supp. 2d at 307-308; *Blackmon v. American Home Products Corp.*, 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004); *Militrano v. Lederle Laboratories*, 3 Misc. 3d 523, 769 N.Y.S.2d 839 (2003), aff'd, 26 A.D.3d 475, 810 N.Y.S.2d 506 (2006). Each of these cases, however, was either decided before or fails to

address the Supreme Court's landmark opinion[5] in *Bates v. Dow AgroSciences*, 544 U.S. 431, 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005), on traditional preemption analysis. The Ferraris assert that application of the reasoning in *Bates*, supra, mandates a different outcome. We agree.

BATES

In *Bates*, the Supreme Court "overturn[ed] thirteen years of precedent during which pesticide companies enjoyed relative immunity from tort liability." Joseph Frueh, Pesticides, Preemption, and the Return of Tort Protection, 23 Yale J. on Reg. 299, 300 (Summer 2006). Before *Bates*, courts interpreted the following language from the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")[6] to bar tort claims: "State[s] shall not impose or continue in effect any requirement for labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). *Bates*, supra, 544 U.S. at 436, nn. 4, 5, 125 S. Ct.

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[5] See Joseph Frueh, Pesticides, Preemption, and the Return of Tort Protection, 23 Yale J. on Reg. 299, 309(V) (Summer 2006) ("*Bates* urges that courts must stay the hand of preemption unless given a nearly explicit mandate by the enabling statute."); Kim Ly, *Bates v. Dow AgroSciences:* Overcoming Federal Preemption and Giving the People a Voice, 26 J. Nat. Assn. Admin. L. Judges 297, 336(VI) (Spring 2006) ("the *Bates* Court has signaled a shift away and against federal preemption of common law tort [claims]"); Christene Beaupre, Case Comment: Product Safety-Food and Drug Laws: How Bates Changed the Face of Preemption, 82 N. Dak. L. Rev. 579, 601(IV)(A) (2006) ("The *Bates* decision may reverse . . . the trend to uphold preemption claims and bar state law claims.") (citation and footnote omitted).

[6] 7 U.S.C. § 136 et seq.

1788. According to this view, judgments in civil actions might compel pesticide companies to change their labels and would therefore violate the prohibition contained in § 136v(b). See id. at 443, 125 S. Ct. 1788.

The Supreme Court rejected this approach, and adopted a "parallel requirements reading" of the phrase "in addition to or different from" in FIFRA to allow civil suits based upon common law standards of conduct that served FIFRA's primary purpose of preventing false or misleading statements or inadequate instructions or warnings. *Bates*, supra, at 447-448, 125 S. Ct. 1788. In so holding, the Supreme Court noted that:

> Conspicuously absent from the submissions by Dow and the United States is any plausible alternative interpretation of "in addition to or different from" that would give that phrase meaning. . . . Even if Dow had offered us a plausible alternative reading of § 136v(b)-indeed, even if its alternative were just as plausible as our reading of that text-*we would nevertheless have a duty to accept the reading that disfavors pre-emption.* "Because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." [Cit.] "In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest." [Cits.]

(Punctuation omitted; emphasis supplied.) Id. at 448-449(III), 125 S. Ct. 1788. The emphasized language above drastically changes traditional preemption analysis.

Before *Bates*, application of a presumption against preemption to questions concerning the scope of an express preemption clause was controversial. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996); *Cipollone v. Liggett Group*, 505 U.S. 504, 545-546, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992) (Scalia, J., concurring in the judgment in part and dissenting in part). Furthermore, the presumption against preemption was rebuttable,[7] and courts examined legislative history to determine Congress's intent with regard to ambiguous language in express preemption clauses.[8]

The pivotal language in *Bates* changed traditional preemption analysis in two ways: (1) There is no longer a rebuttable *presumption* against preemption, but a *duty to accept* the reading of an express preemption statute that disfavors preemption; and (2) preemption analysis ends with an examination of the statutory language alone. Under this approach, it appears that legislative history should no longer be examined to discern Congressional intent when an express preemption clause has two plausible alternative readings.

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[7] See, e.g., *Patrick Fur Farm v. United Vaccines*, 286 Wis.2d 774, 780, n. 2, 703 N.W.2d 707 (Wis. App. 2005).

[8] See, e.g., *Sykes*, supra, 484 F. Supp. 2d at 304.

Since *Bates*, one court has adopted these changes into its preemption analysis. See *Blue Flame Energy Corp.*, 171 Ohio App.3d 514, 534, 871 N.E.2d 1227 (2006) ("[I]f the express preemption provision is ambiguous, a court has a duty to accept the reading that disfavors pre-emption, particularly in areas of traditional state regulation.") (citations omitted). While adopting these changes, however, the Ohio Court of Appeals did not apply them, because it concluded that the express preemption clause before it was unambiguous. Id. at 532, 871 N.E.2d 1227. Therefore, if we conclude that the Vaccine Act's preemption clause is subject to two alternative readings, this court may be the first to apply the changes created by *Bates*.

APPLICATION OF *BATES* TO THE VACCINE ACT

The statutory language at issue provides: "No vaccine manufacturer shall be liable in a civil action . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). Two of the courts addressing this language have concluded that two alternative, plausible readings exist with regard to preemption of the issue of unavoidable side effects, and we agree with their conclusion. *Sykes*, supra, 484 F. Supp. 2d at 304; *Militrano*, supra, 769 N.Y.S.2d at 843-844. One reading is that vaccine injuries are "unavoidable" and subject to preemption if the vaccine was properly prepared and accompanied by proper directions and warnings. The other reading is that

design defect claims are preempted only if the side effects are determined to be unavoidable on a case-by-case basis.

We also agree with our fellow courts' conclusion that when the contemporaneous legislative history of the Vaccine Act is examined, Congress's intent to preempt this issue becomes clear.[9] *Skyes*, supra, 484 F. Supp. 2d at 308-309; *Militrano*, supra, 769 N.Y.S.2d at 843-844. A passage in the Report of the Committee on Energy and Commerce states:

> Given the existence of the compensation system in the Vaccine Act, ... [v]accine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings they should pursue recompense in the compensation system, not the tort system.

(Punctuation omitted.) *Sykes*, supra, 484 F. Supp. 2d at 300. See also *Militrano*, supra, 810 N.Y.S.2d at 508; *Blackmon*, supra, 328 F. Supp. 2d at 664-665.

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[9] The Ferraris point to subsequent legislative history accompanying an amendment to fund the Vaccine Act as evidence of a contrary intent. However, "subsequent legislative history is a hazardous basis for inferring the intent of an earlier Congress." (Citation and punctuation omitted.) *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 650(III)(B), 110 S. Ct. 2668, 110 L. Ed. 2d 579 (1990).

1. Because two alternative readings of the Vaccine Act exist, application of the Supreme Court's pronouncement in *Bates*, supra, is outcome determinative.[10] Under *Bates*, we "have a duty to accept the reading [of the Vaccine Act] that disfavors pre-emption," and we cannot resort to an examination of legislative history to discern Congress's intent. 544 U.S. at 449(III), 125 S. Ct. 1788. Because two plausible, alternative readings of the Vaccine Act exist, we must conclude that the trial court erred by finding that the Ferraris' design defect claims are preempted.

While this result differs from that reached by other courts addressing the preemptive effect of the Vaccine Act, none of those courts addressed the impact of *Bates* on the analysis of ambiguous express preemption clauses. We recognize that this result is anomalous given the clear legislative history to the contrary, but we are constrained to follow the Supreme Court's explicit guidance in *Bates*. While the vaccine defendants urge us to limit the Supreme Court's pronouncement in *Bates* to the facts of the case before it, there is no rational basis for us to do so. The language at issue is very broad and addresses preemption analysis generally.

2. Our holding in Division 1 renders moot the Ferraris' remaining enumeration of error regarding

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[10] The vaccine defendants assert that *Bates* should be limited to its facts and apply only in cases involving the same or similar preemption statutes. We find no merit in the argument. The language used by the Supreme Court in *Bates* is very broad and applies to the analysis of any express preemption statute.

the trial court's refusal to consider their constitutional claims.

Judgment reversed.

BARNES, C.J., and MILLER, J., concur.

APPENDIX C

IN THE STATE COURT OF FULTON COUNTY, STATE OF GEORGIA

MARCELO A. FERRARI and CAROLYN H. FERRARI, Individually and as Parents and Next Friend of STEFAN R. FERRARI,

Plaintiffs,

v.

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH; WYETH LABORATORIES; WYETH-AYERST; WYETH-AYERST LABORATORIES; WYETH LEDERLE; WYETHER LEDERLE; WYETHER LEDERLE VACCINES AND LEDERLE LABORATORIES; ORTHO-CLINICAL DIAGNOSTICS, INC.; SMITHKLINE BEECHAM CORPORATION; GEORGIA POWER COMPANY; and JOHN DOES 1-20 who are individuals, proprietorships, corporations or other entities whose names and identities are otherwise unknown to the plaintiffs

Defendants.

CIVIL ACTION FILE
NO. 02 VS 031404-F.

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS WYETH, SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, AND GLAXOSMITHKLINE BIOLOGICALS S.A.'S MOTION FOR SUMMARY JUDGMENT, OR ALTERNATIVELY, MOTION TO DISMISS OR REQUIRE REPLEADING OF ALLEGATIONS

Plaintiffs allege in this product liability action that the minor plaintiff suffers from a neurological condition that was caused, in part, by exposure to FDA-approved vaccines containing the preservative thimerosal. Before the Court is a Motion for Summary Judgment, or Alternatively, Motion to Dismiss or Require Repleading of Allegations filed by Defendants WYETH (f/k/a AMERICAN HOME PRODUCTS CORPORATION), SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE and GLAXOSMITHKLINE BIOLOGICALS S.A. (collectively the "Vaccine Defendants"). The Vaccine Defendants argue that the Court should grant summary judgment because the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-1 *et seq.* (*hereinafter* the "Vaccine Act"), pre-empts all of Plaintiffs' claims. The Vaccine Defendants assert that all of Plaintiffs' claims, including failure to warn, are pre-empted by Section 22(b) of the Vaccine Act because the claims are all based on a singular

design defect allegation, *i.e.*, that the FDA-approved vaccines at issue should not have contained the preservative thimerosal. The Vaccine Defendants also contend that Section 22(c) of the Vaccine Act bars Plaintiffs' claims for failure to warn Plaintiffs and the general public. The Vaccine Defendants additionally seek dismissal of Plaintiffs' fraud-based allegations pursuant to O.C.G.A. §§ 9-11-9(b) and 9-11-12 for failure to plead such allegations with particularity.

In support of their Motion, the Vaccine Defendants filed a memorandum, a statement of material facts and theories of recovery, the affidavit of Karen Raby Monson with attached exhibits A-H, and a reply memorandum in further support of their Motion. Plaintiffs filed a brief in opposition to the Motion and a response to the Vaccine Defendants' statement of material facts and theories of recovery. The Court has reviewed the papers submitted by each party, and on July 8, 2005, the Court heard oral argument on the Motion from counsel. At the conclusion of the argument, the Court ruled on the Vaccine Defendants' Motion. This Order reflects that ruling and the Court's supporting reasons. For the reasons that follow, the Vaccine Defendants' Motion for Summary Judgment, or Alternatively, Motion to Dismiss or Require Repleading of Allegations is hereby **GRANTED IN PART** and **DENIED IN PART**.

BACKGROUND

On or about April 15, 2002, plaintiffs Marcelo and Carolyn Ferrari, individually and on behalf of the

minor plaintiff, Stefan R. Ferrari, commenced the instant proceeding by filing a complaint alleging that the minor plaintiff allegedly suffers from a neurological condition, which Plaintiffs claim was caused by exposure to FDA-approved vaccines containing the preservative thimerosal. Plaintiffs asserted claims under Georgia law for strict tort liability, negligence, fraud and deceit, negligent misrepresentation, and breach of warranty. Plaintiffs also sought punitive damages based upon assertions of gross negligence.

This Court dismissed without prejudice the claims of the minor plaintiff on January 6, 2003. On February 20, 2003, all discovery in this case was stayed until further order of the Court. On October 15, 2003, this Court dismissed without prejudice the claims alleged by the parent plaintiffs (other than their separate state law claims for loss of services and emotional distress). The dismissals afforded Plaintiffs the opportunity to file a petition in Vaccine Court. In October 2004, Plaintiffs, having filed a Vaccine Court petition, elected to terminate their proceeding in that forum and filed a Second Amended Complaint on October 25, 2004, asserting that they had "complied with all prerequisites under the National Vaccine Injury Compensation Act." The Court lifted the stay of proceedings on April 20, 2005.

The Vaccine Defendants filed the motion for summary judgment that is the subject of this Order on May 27, 2005, and filed a corrected Motion on

May 31, 2005.[1] Plaintiffs filed their brief in opposition on July 1, 2005, and the Vaccine Defendants filed a reply memorandum in further support of their Motion on July 7, 2005.

DISCUSSION

A. *The Vaccine Act*

Childhood vaccines play a central role in national health policy, and the Vaccine Act, which covers Plaintiffs' claims here, is integral to that policy. In 1986, the United States Congress passed the Vaccine Act, and created "a new system for compensating individuals who have been injured by vaccines routinely administered to children." H.R. Rep. 99-908, 99th Cong., 2d Sess. (1986), at 3, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344. The Vaccine Act's legislative history documents the concerns that spurred enactment of the law. It notes the inability of the tort system to predictably and properly deal with claims on behalf of children alleging vaccine-related injuries, and that costly litigation without predictable results created an incentive for vaccine manufacturers to withdraw from making childhood vaccines critical to public health. *See id.* at 6344-48; *see also Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1116-17 (4th Cir. 1988) (Wilkins, J., concurring) ("As a . . . consequence of the increase in litigation, . . . manufacturers are reconsidering their

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[1] GlaxoSmithKline Biologicals s.a. ("Biologicals") did not appear in this action until it filed an answer with this Court on July 7,2005. At that time, Biologicals also filed a notice of joinder in the Vaccine Defendants' Motion.

future role in the vaccine market. The withdrawal of any manufacturer from the market poses a serious threat to public health, in the form of vaccine shortages with resulting decreased immunization and a possible resurgence of these diseases.").

The Vaccine Act reflects two specific policy goals of Congress. First, the federal legislative scheme aimed to simplify the procedure and the substantive rules of law applicable to vaccine-related injury claims, and so make it easier for injured parties to obtain compensation. To implement this policy, Congress established a special court ("Vaccine Court") as part of the United States Court of Federal Claims to adjudicate claims of "vaccine-related injury"[2] and to award compensation to injured individuals. *See Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995) ("For injuries and deaths traceable to vaccinations, the [Vaccine] Act establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system."). A claimant may recover by proving an injury plus causation. Proof that the vaccine at issue was negligently manufactured, defectively designed, or inadequately

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[2] "Vaccine-related injury" "means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. § 300aa-33(5). It includes claims alleging injury from thimerosal contained in FDA-approved vaccines. *See, e.g., Blackmon v. Am. Home Prods. Corp.*, 267 F. Supp. 2d 667, 673-75 (S.D. Tex. 2002); *Leroy v. Sec'y of HHS*, No. 02-392V, 2002 WL 31730680, at * 17 (Fed. Cl. Oct. 11, 2002); *Ashton v. Aventis Pasteur, Inc.*, 851 A.2d 908, 911-13 (Pa. Super. Ct. 2004).

labeled is not required to obtain compensation on any Vaccine Court petition. *See* 42 U.S.C. §§ 300aa-11(c)(1); 300aa-13(a)(1). Approximately 4,500 petitions seeking compensation based on allegations that thimerosal-containing vaccines and/or the Measles-Mumps-Rubella ("MMR") vaccine caused autism or autism spectrum disorder are currently pending before the Vaccine Court. *See In re Claims For Vaccine Injuries Resulting In Autism Spectrum Disorder Or A Similar Neurodevelopmental Disorder*, Autism Master File – Autism Update (Ct. Fed. Cl. June 27, 2005) (Hastings, S.M.).

Second, Congress intended to protect the supply of childhood vaccines in the United States by protecting vaccine manufacturers from the burden of costly litigation with unpredictable outcomes. The Vaccine Act protects vaccine manufacturers from costly civil litigation by: (i) barring civil actions such as this arising from vaccine-related injuries unless the claim was first presented in the Vaccine Court and the remedy exhausted[3]; (ii) immunizing vaccine manufacturers from liability for alleged vaccine-related injuries caused by vaccines that were properly prepared and accompanied by proper directions and warnings; and (iii) establishing legal presumptions as to the adequacy of vaccine warnings and against the imposition of punitive damages except in cases involving substantial wrongdoing.

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[3] Congress expected that a significant number of claims would be resolved in the Vaccine Court forum under the Vaccine Act's provisions for generous compensation. *See* 1986 U.S.C.C.A.N. at 6354.

See 42 U.S.C. §§ 300aa-11; 300aa-22; 300aa-23(d); *see also* 1986 U.S.C.C.A.N. at 6367. In addition to requiring that any vaccine-related injury claim be first presented in Vaccine Court, the Vaccine Act sets substantive and procedural rules that control the conduct of every civil action on claims of injury arising from post-October 1, 1988 vaccine administrations. Those limitations bar certain claims – including certain of the claims Plaintiffs assert in their Complaint – from being litigated in any civil action.

B. *The Vaccine Act's Express Pre-emption Of State Products Liability Law*

The Vaccine Defendants argue that Section 22 of the Vaccine Act pre-empts all state law design defect claims arising from vaccine-related injuries. Plaintiffs contend that the Vaccine Act merely supplements state products liability law, rather than displacing it. For the reasons set forth, the Court concludes that the Vaccine Act pre-empts all claims based on a theory of design defect.

Federal law may pre-empt state law in three ways:

> First, in enacting the federal law, Congress may explicitly define the extent to which it intends to preempt state law. (Citation omitted.) Second, even in the absence of express pre-emptive language, Congress may indicate an intent to occupy an entire field of regulation, in which case the states must leave all regulatory activity in that area to the Federal Government. (Citations

> omitted.) Finally, if Congress has not displaced state regulation entirely, it may nonetheless pre-empt state law to the extent that the state law actually conflicts with federal law.

Mich. Canners & Freezers Ass'n, Inc. v. Agric. Mktg. & Bargaining Bd., 467 U.S. 461, 469 (1984).

Section 22 of the Vaccine Act is an example of express pre-emption, as indicated by Section 22(a), which states that: "Except as provided in subsections [22](b), [22](c), and [22](e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a).

Section 22(b)(1) of the Vaccine Act states:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1). That section states the express limitation on civil actions against vaccine manufacturers: it bars all civil actions arising from a vaccine-related injury if the injury could not have been avoided by proper preparation or proper labeling of the vaccine.

The cases Plaintiffs cite for the proposition that the Vaccine Act does not pre-empt state tort law are inapposite. The claims in those cases arose before the effective date of the Vaccine Act and concern vaccinations administered before October 1, 1988. The issue in those cases was whether state law claims had been impliedly pre-empted by federal law. Thus, the cases do not address whether Section 22 of the Vaccine Act expressly pre-empts design defect claims. *See Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 246-47 (E.D. Pa. 1990); *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1113-14 (4th Cir. 1988); *Hurley v. Lederle Labs. Div. of American Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1989).

C. *Plaintiffs' Design Defect Claims*

With regard to Plaintiffs' design defect claims, the only issue before the Court is the extent of the pre-emptive effect of Section 22(b) of the Vaccine Act. Plaintiffs contend that Section 22(b)(1) simply codifies Comment k of Section 402A of the Restatement (Second) of Torts and directs states to determine under their tort law whether an alleged vaccine-related injury or death resulted from side effects that were unavoidable under any circumstances, including design standards that might be imposed by state tort law. Plaintiffs maintain that the Vaccine Act only bars their design defect claims here if the Court determines under Georgia products liability law that the side effects of the vaccines at issue are unavoidable.

Plaintiffs construe the statute as if it ended with the words "side effects that were unavoidable." The statute continues, however, that vaccine manufacturers are not subject to civil liability where the alleged "injury or death resulted from side effects that were *unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.*" 42 U.S.C. § 300aa-22(b)(1) (emphasis added). Plaintiffs' interpretation therefore does not account for all elements of the statute. *See Gilbert v. Richardson*, 264 Ga. 744, 747-48, 452 S.E.2d 476, 479 (1994) ("It is a basic rule of construction that a statute. . . should be construed 'to make all its parts harmonize and to give a sensible and intelligent effect to each part.'" (citation omitted)). By its express terms, the statute immunizes vaccine manufacturers from liability for side effects that inevitably occur even though a vaccine is properly prepared in every respect according to its approved design specifications and is properly labeled. Thus, a manufacturer that properly prepares and labels a vaccine in accordance with the applicable federal law is immune from civil liability for side effects that nonetheless occur, even if, theoretically, an alternatively-designed vaccine might have prevented the alleged injury.

To date, two other cases have addressed the pre-emptive impact of the Vaccine Act on claims arising from vaccine-related injuries attributed to FDA-approved pediatric vaccines, *Blackmon v. American Home Products Corp.* and *Militrano v. Lederle Laboratories*. This Court's interpretation of Section 22 is in accord with the holdings of both *Blackmon* and *Militrano*. *See Blackmon v. American Home*

Prods. Corp., 328 F. Supp. 2d 659, 663-66 (S.D. Tex. 2004) (holding that Section 22(b) forecloses all design defect claims against vaccine manufacturers); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845 (Sup. Ct. Kings Co. 2003) (holding that Section 22(b) bars all design defect claims because "Congress did not intend that national vaccine policy be determined by the vagaries of a jury's determination on a case-by-case basis").

Plaintiffs contend that the Georgia Court of Appeals in *Bryant v. Hoffman-LaRoche, Inc.* has already decided that federal law does not pre-empt civil actions alleging injury caused by defectively designed prescription drugs, including vaccines. *Bryant*, however, did not mention, much less interpret, the Vaccine Act, and thus could not have decided whether the Vaccine Act bars design defect claims arising out of a *vaccine-related injury*. *See Bryant v. Hoffman-LaRoche, Inc.*, 262 Ga. App. 401, 585 S.E.2d 723 (2003). Indeed, *Bryant* involved the heart medication Posicor, not a pediatric vaccine. *See id.* at 401, 585 S.E.2d at 725. *Bryant* held that Georgia courts should determine whether a prescription drug is "unavoidably unsafe" under Comment k of Section 402A of the Restatement (Second) of Torts on a case-by-case basis. *See id.* at 406; 585 S.E.2d at 728.

While Congress clearly looked to the principles contained in Comment k of Section 402A of the Restatement (Second) of Torts when drafting Section 22(b) of the Vaccine Act, Congress did not codify the exact language of Comment k or adopt the interpretation some Georgia courts have given to

Comment k.[4] *Compare* Restatement (Second) of Torts § 402A cmt. k (2002) (stating, with respect to a vaccine, that "[s]uch a[n unavoidably unsafe] product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous") *with* 42 U.S.C. § 300aa-22(b)(1) (providing that "[n]o vaccine manufacturer shall be liable" for alleged "injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."). Nor did Congress leave vaccine design standards open to reexamination under the laws of each state, with the potential for interstate conflict: the Vaccine Act sets one rule, applicable nationwide, that pre-empts design defect claims.

Congress intended that "the principle in Comment K regarding 'unavoidably unsafe' products, *i.e.*, those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the [Act] and *that such products not be the subject of liability in the tort system*." 1986 U.S.C.C.A.N. at 6367

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[4] Comment k and Section 22(b)(1) differ in two notable aspects. First, Comment k refers to "unavoidably unsafe" products, while Section 22(b)(1) does not use that term. Second, while Comment k's language is directed to strict liability claims, Section 22(b)'s plain language is all-encompassing, including claims grounded in negligence, as well as those based on strict liability. Section 22(b)(1)'s statement that "no manufacturer shall be liable in a civil action for damages" plainly bars all claims based on the alleged design defect, whether characterized as negligence, strict liability, or by any other legal label. *See Blackmon*, 328 F. Supp. 2d at 665-66.

(emphasis added). Thus, the view of Comment k that Congress adopted when it enacted Section 22(b) immunizes manufacturers of "properly prepared" products that are "accompanied by proper directions and warnings" from all design defect claims. That statutory standard, not the common law case-by-case approach advocated by certain Georgia courts, governs the Court's analysis here. *See Militrano*, 769 N.Y.S.2d at 845 (stating that "the language in the House Committee report supports the conclusion that Congress intended to view Comment k and the [Vaccine] Act as immunizing vaccines from liability for design defects.").

The legislative history of Section 22 that is contemporaneous with that 1986 enactment confirms Congress's intention as expressed in Section 22(b):

> Given the existence of the compensation system in [the Vaccine Act], the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. *Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.*

H.R. Rep. No. 99-908, 99th Cong., 2d Sess. (1986), at 4, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6367 (emphasis added); *see also Blackmon*, 328 F. Supp. 2d at 665 (finding that the relevant legislative history "rather clearly" indicates that the Act bars design defect claims).[5]

The intent to establish one national standard for vaccine design and to remove that from the purview of state tort law is further demonstrated by the Vaccine Act's specific delegation of questions of vaccine safety to the Secretary of Health and Human Services. *See* 42 U.S.C. § 300aa-27; *see also* 42 U.S.C. § 300aa-2(a)(2) (directing HHS to coordinate and direct programs to develop safe and

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[5] Plaintiffs rely on statements from a subcommittee report from 1987, the year after enactment of the Vaccine Act, as evidence of Congress's intent, in 1986, in adopting the Act. See H. R. Rep.100-391(I), at 691, reported in 1987 U.S.C.C.A.N. at 2313 365. The Court concludes that the 1987 statements are not entitled to any weight. Post-enactment statements are not reliable indicators of earlier congressional intent, particularly where, as here, they do not relate to any legislation passed at the time that the statements are made. *See, e.g., Pension Benefit Guar. v. LTV Corp.*, 596 U.S. 633, 650 (1990) ("[S]ubsequent legislative history is a 'hazardous basis for inferring the intent of an earlier' Congress"); *see also Ewing & Thomas, P.A. v. Heye*, 803 F.2d 613, 616 (11th Cir. 1986). The 1987 statements, as interpreted by Plaintiffs, directly contradict the 1986 legislative history of Section 22 cited above, which explicitly rejects Plaintiffs' argument that Section 22(b)(1) permits design defect claims. Furthermore, the statements do not assist the Court in construing Section 22(b)(1) because the statements do not track the language of Section 22(b)(1), referring instead to "unavoidably unsafe" vaccines.

effective vaccines).[6] Section 27 mandates that HHS "promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 27, 1987, and promote the refinement of such vaccines." *Id.* § 300aa-27(a)(1). It further directs the Secretary to "make or assure improvements . . .in the licensing, manufacturing, processing, testing, labeling, warning, . . . and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." *Id.* § 300aa-27(a)(2). Section 27 also directs HHS to "establish a task force on safer childhood vaccines," consisting of "the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control," which is to consult with the Advisory Commission on Childhood Vaccines to make recommendations to increase vaccine safety and efficacy. *Id.* § 300aa-27(b).

The FDA's authority to determine the uniform national design for childhood vaccines would be

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[6] *See also* 42 U.S.C. § 300aa-1 ("The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."); *Id.* § 300aa-5 (establishing the National Vaccine Advisory Committee, which, *inter alia*, studies and recommends "ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States); *Id.* § 300aa-19 (establishing the Advisory Commission on Childhood Vaccines to, *inter alia*, "advise the Secretary in implementing the Secretary's responsibilities under section 300aa-27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions.").

undermined if these Plaintiffs were allowed to challenge vaccine design under Georgia law (or under any state's law). Section 22(b) is properly read to foreclose all design defect claims against vaccine manufacturers in order to prevent plaintiffs from mounting such a collateral attack on FDA decisions through the tort system.

Accordingly, this Court enters summary judgment dismissing all of Plaintiffs' design defect claims. The dismissal of Plaintiffs' design defect claims is not limited to Plaintiffs' strict liability design defect and negligent design claims. Plaintiffs' failure to warn, fraud, gross negligence, and breach of warranty claims are also barred by Section 22(b)(1) to the extent that those claims are based solely on the inclusion of thimerosal in the design of the vaccines at issue.

D. *Plaintiffs' Failure-To-Warn Claims*

The Vaccine Defendants argue that Section 22(c) of the Vaccine Act explicitly forecloses Plaintiffs' claims based on a duty to provide direct warnings to Plaintiffs and the general public. Section 22(c) provides that:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential

> dangers resulting from the administration of the vaccine manufactured by the manufacturer.

42 U.S.C. § 300aa-22(c). To the extent that Plaintiffs' failure-to-warn claims are based on allegations that the Vaccine Defendants failed to warn Plaintiffs or the public generally, they are hereby dismissed.

The Vaccine Defendants further argue that all of Plaintiffs' failure-to-warn claims restate their design defect claims. Plaintiffs' Complaint alleges that thimerosal is a "powerful and dangerous neurotoxin poison." Compl. ¶ 9. The Vaccine Defendants contend that Plaintiffs' theory is no warning could have made safe any universally-administered childhood vaccine containing what is alleged to be a "dangerous neurotoxin poison."

In order for Plaintiffs to allege a valid failure-to-warn claim, they must assert that the vaccines at issue could have been sold safely if they contained a warning about thimerosal. *See Center Chem. Co. v. Parzini*, 234 Ga. 868, 870, 218 S.E.2d 580, 582 (1975). As currently pled, Plaintiffs' failure-to-warn claims are essentially a restatement of their design defect claims, which are barred by Section 22(b)(1) of the Vaccine Act. The Court concludes, however, that Plaintiffs should have another opportunity to plead a failure-to-warn claim that could satisfy the notice pleading standard of O.C.G.A. § 9-11-8. Therefore, the Court **GRANTS** Plaintiffs leave to replead this claim by way of an amended Complaint to be filed with the Court within fifteen (15) days of the date of

this Order. The amended Complaint should assert allegations beyond the fact that the vaccines at issue contain thimerosal and should also clarify the nature of the warnings that Plaintiffs contend the vaccines at issue required.[7] Plaintiffs should be afforded the opportunity to conduct discovery related to their amended failure-to-warn claims that is consistent with the provisions of Section 22(b)(2) of the Vaccine Act. The Vaccine Defendants, however, may present another motion for summary judgment on Plaintiffs' failure-to-warn claims after discovery pertinent to that issue has been conducted.

E. *Plaintiffs' Manufacturing Defect Claims*

The Vaccine Defendants argue that Plaintiffs have failed to allege a valid manufacturing defect claim. Plaintiffs' Complaint simply states that the vaccines were "defectively designed, manufactured, marketed and distributed." Compl. ¶ 28. Plaintiffs disagree, contending that they have adequately plead a manufacturing defect claim and that they are entitled to conduct discovery with regard to that claim.

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[7] Plaintiffs allege in their complaint that the Vaccine Defendants "impliedly and expressly warranted to the Plaintiffs that these Thimerosal-containing products . . . were safe, when in fact, the products were not safe. Each of [the Vaccine Defendants] was negligent for distributing a defective product without providing adequate warnings and without first determining that the products were safe." Compl. ¶ 53. In light of this Court's ruling that Section 22(b)(1) bars all design defect claims, Plaintiffs' breach of warranty claim would only be viable to the extent it alleges that the vaccines at issue were defective due to inadequate warnings.

"[A] manufacturing defect will always be identifiable as a deviation from some objective standard or a departure from the manufacturer's specifications established for the creation of the product." *Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1236 (N.D. Ga. 2002). Because thimerosal is part of the FDA-approved formula for the vaccines at issue, Plaintiffs cannot contend that the inclusion of thimerosal was a manufacturing defect in the vaccines at issue and the cause of Plaintiffs' injuries. To the extent that Plaintiffs' manufacturing defect claims are based on the inclusion of thimerosal, they are barred by Section 22(b) as repackaged design defect claims. The Court concludes, however, that Plaintiffs' manufacturing defect allegations satisfy the notice pleading requirements set forth by O.C.G.A. § 9-11-8. Plaintiffs would need to prove a defect in manufacturing, to sustain their claim, and not just that the vaccine contained thimerosal as part of its formula. The Vaccine Defendants may present another motion for summary judgment on Plaintiffs' manufacturing defect claims after discovery pertinent to that issue has been conducted.

F. *Plaintiffs' Fraud-Based Claims, Gross Negligence Claim, And Punitive Damages Claim*

The Vaccine Defendants have moved to dismiss Plaintiffs' fraud-based claims on the ground that they contain unspecified and unattributed allegations of fraud that do not meet the standard set forth by O.C.G.A. § 9-11-9(b). *See R.W. Holdco, Inc. v. Johnson*, 267 Ga. App. 859, 866, 601 S.E.2d

177, 185 (2004). While the Complaint lacks any reference to particular false statements made or specific information concealed, and groups all defendants together into conclusory paragraphs, *See* Compl ¶¶ 46, 47, the Court will allow Plaintiffs fifteen days from the date of this Order to replead by way of an amended Complaint to be filed with the Court within fifteen (15) days of the date of this Order.[8]

For the same reasons, Plaintiffs have leave to replead their gross negligence and punitive damage claims. The Vaccine Act precludes the imposition of punitive damages on vaccine manufacturers absent a showing of "fraud or intentional and wrongful withholding of information" during the regulatory process or "other criminal or illegal activity relating to the safety and effectiveness of vaccines." 42 U.S.C. § 300aa-23(d)(2). Such claims must be pled in accordance with the particularity requirements of O.C.G.A. § 9-11-9(b). Plaintiffs shall have fifteen (15) days from the date of this Order to file an amended Complaint.

G. *The Parent Plaintiffs' Claims*

Plaintiffs argue that even if minor plaintiff's claims are barred, the parent plaintiffs' claims for

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[8] The Vaccine Defendants allege that there is an issue of whether Plaintiffs have standing to allege their fraud claims here. Pursuant to Section 22(c) of the Vaccine Act, the Vaccine Defendants argue that they have no duty to warn Plaintiffs or the general public of any potential dangers resulting from the administration of the vaccines at issue.

loss of services, infliction of emotional distress, and medical expenses incurred for minor plaintiff are not subject to the liability limitations of Section 22(b). This argument ignores the plain language of Section 22(b), which expressly extends to *any* "civil action [against a vaccine manufacturer] for damages arising from a vaccine-related injury" associated with a vaccine administered after October 1, 1988. *See* 42 U.S.C. § 300aa-22(b)(1). Because the parent plaintiffs' claims necessarily arise from minor plaintiff's alleged "vaccine-related injury," they are subject to the liability limitations of Section 22(b)(1) of the Act by its explicit terms. The case relied upon by Plaintiffs, *Moss v. Merck & Co.*, 381 F.3d 501 (5th Cir. 2004), is inapposite. That case concerned whether the pre-suit administrative exhaustion provisions imposed by Section 11 of the Vaccine Act extended to independent parental claims that could not be presented in Vaccine Court. Id. at 504-05. It does not matter, for purposes of applying Section 22, whether or not the parent plaintiffs' claims could or could not have been asserted in administrative compensation proceedings. Therefore, these claims are **DISMISSED WITH PREJUDICE**.

CONCLUSION

For the reasons stated above, Defendants Wyeth (f/k/a American Home Products Corporation), SmithKline Beecham Corporation d/b/a GlaxoSmithKline, and GlaxoSmithKline Biologicals s.a.'s Motion for Summary Judgment, or Alternatively, Motion to Dismiss or Require Repleading of Allegations is hereby **GRANTED IN PART** and **DENIED IN PART**. Plaintiffs' design

defect claims are **DISMISSED WITH PREJUDICE** pursuant to Section 22(b)(1) of the Vaccine Act. Plaintiffs' failure-to-warn claims are hereby **DISMISSED WITH PREJUDICE** to the extent that they allege a failure to warn Plaintiffs or the general public. The remainder of Plaintiffs' failure-to-warn claims, in addition to their fraud, gross negligence, and punitive damage claims are hereby **DISMISSED WITHOUT PREJUDICE** with leave to replead. Plaintiffs' breach of warranty claims are **DISMISSED WITH PREJUDICE** to the extent that they allege that the vaccines at issue were defective solely due to their design. The claims alleged individually by the parent plaintiffs are **DISMISSED WITH PREJUDICE** pursuant to Section 22(b)(1) of the Vaccine Act. To the extent that Plaintiffs' manufacturing defect claims are based on the inclusion of thimerosal in the vaccines at issue, they are hereby **DISMISSED WITH PREJUDICE**. As there is no just reason for delay, it is directed that final judgment be immediately entered on the claims herein dismissed with prejudice. The Vaccine Defendants' motion for summary judgment on the remainder of Plaintiffs' manufacturing defect claims is **DENIED**.

SO ORDERED this 30th day of November, 2005.

/s/ Susan B. Forsling

SUSAN B. FORSLING
Judge, State Court of
Fulton County